

Affordable Medicines Facility-malaria (AMFm) Phase 1

AMFm Review and the Financing of Febrile Illness Management
Washington, DC 17 September 2012

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Key events leading to the start of Phase 1

Following the 2004 IOM Report *Saving Lives, Buying Time:*

- **2006** RBM Partnership fostered multi-institutional process leading to **AMFm Technical Design** approved by RBM Board in **November 2007**
 - Included the addition of “supporting interventions” to promote the appropriate use of ACTs
- **Hosting and management by the Global Fund**
 - **2008** Global Fund Board requested the Secretariat to begin operations (GF/B17/DP16)
 - **2009** select countries invited to submit applications and following Technical Review Panel recommendations Global Fund Board approves applications
 - **By mid 2010**, Global Fund grant amendment processes completed for each pilot to permit initiation of country-level operations

AMFm goals and objectives

Goal 1: Contribute to Malaria Mortality Reduction

Goal 2: Delay Resistance to Artemisinin

Four objectives:

1 – Increasing availability of quality-assured ACTs

- Working through public, private for-profit and private not-for-profit sectors

2 – Increasing affordability of quality-assured ACTs

3 – Increasing market share of quality-assured ACTs

- Decrease likelihood of artemisinin resistance by crowding out oral artemisinin monotherapies

4 – Increasing use of quality-assured ACTs

- Including among vulnerable populations

Phase 1 is a “Test of Concept”

AMFm comprises three elements:

1) Negotiations with ACT manufacturers

- Reduce prices to same price for public + private sector first-line buyers
- Negotiation on maximum prices per formulation; same prices across all manufacturers

2) Buyer subsidy (co-payments) at top of global supply chain

- Further reduce price of ACTs to first line buyers
- Fixed co-payment amount per formulation; same for all manufacturers

3) “Supporting interventions” to ensure effective ACT scale-up

Uses all sectors: public, private non-profit, private for-profit

Operational in nine pilots in eight countries:

Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (mainland and Zanzibar), Uganda

How is the AMFm financed?

AMFm Co-Payment Fund (for the subsidy)

- US\$ 216 million (July 2010 – Feb 2012)
- US\$ 120 million (Mar 2012 – Dec 2012)
- Financed by
 - UNITAID
 - United Kingdom (DFID)
 - Bill and Melinda Gates Foundation
 - Canadian International Development Agency (CIDA)



Global Fund “general pool” (for supporting interventions)

- Up to US\$ 126.7 million

Supporting Interventions

Proposed by countries in AMFm application

- *Required interventions for Phase 1:*
 - **Public awareness and education** interventions for ACT treatment
 - **Provider training, supervision and ongoing support** (multi-sector) to promote safe and effective use of ACTs
 - Support for **national drug monitoring** (e.g., pharmacovigilance)
 - Support for **national policies and regulations**
 - **Reaching poor people** and other vulnerable groups
- *Additional interventions also encouraged*
 - Some countries requested funds to support the scale-up of access to malaria diagnostics as part of their AMFm application

AMFm logo

- Manufacturers print AMFm logo on all co-paid ACT packages and blisters
- Intended to:
 - Facilitate identification of co-paid products
 - Support marketing and public awareness efforts through displays in newspapers, posters, television and billboards
- May also facilitate identification of leakage to non-AMFm countries

Co-payment process

- 1) Order agreed:** First-line buyer and manufacturer reach an agreement on an order (e.g., quantity, formulation, pack size, delivery schedule, etc.)
- 2) Co-payment requested:** Manufacturer submits a request for co-payment to the Global Fund (including freight and insurance)
- 3) Co-payment confirmed:** Global Fund performs due diligence on the request and may respond with a “confirmation of co-payment”
- 4) Order fulfilled:** Manufacturer proceeds with filling order
- 5) Order delivered:** First-line buyer receives the order and manufacturer submits “proof of delivery” to the Global Fund
- 6) Global Fund co-payment paid:** Global Fund, upon receipt of proof of delivery, makes payment to manufacturer of co-payment amount
- 7) First-line buyer portion paid:** First-line buyer submits payment to manufacturer for the balance owed (or this step may be done pre-delivery)

“Typical” ordering behavior: public and private sector differences



Key difference	Public sector buyers	Private sector buyers
Frequency	Single order placed for entire year (with staggered deliveries)	Several orders placed throughout the year
Order size	Entire public sector need in one order	Part of private sector need through multiple smaller orders
Competition	Competitive tender required	Can (and may be obliged to) engage directly with preferred suppliers

For example, between June 2010 and Dec 2011, in Kenya:

- *one public sector buyer placed 2 orders for a total of 16.5 million ACTs; and*
- *six for-profit buyers placed 34 orders for a total of 16 million ACTs.*

ACTs Approved and Delivered by Sector

[As of 31 Dec 2011]

At global level:

Sector	Treatments Approved for co-payments (millions)	Treatments Delivered (millions)
Public	58.6	52.7
Private for-profit	132.5	98.3
Private not-for-profit	7.4	6.5
<i>Total</i>	<i>198.6</i>	<i>157.5</i>

Within countries:

Some public sector entities (facility- and district-level) buy from private sector First Line Buyers to avoid stock-outs from delays in public sector/CMS procurement through imports

Examples: Ghana, Niger, Nigeria and Tanzania

ACTs Approved and Delivered by Sector

[As of 31 August 2012]

At global level:

Sector	Treatments Approved for co-payments (millions)	Treatments Delivered (millions)
Public	74.7	64.3
Private for-profit	208.6	160.6
Private not-for-profit	10.5	10.2
<i>Total</i>	<i>293.8</i>	<i>235.1</i>

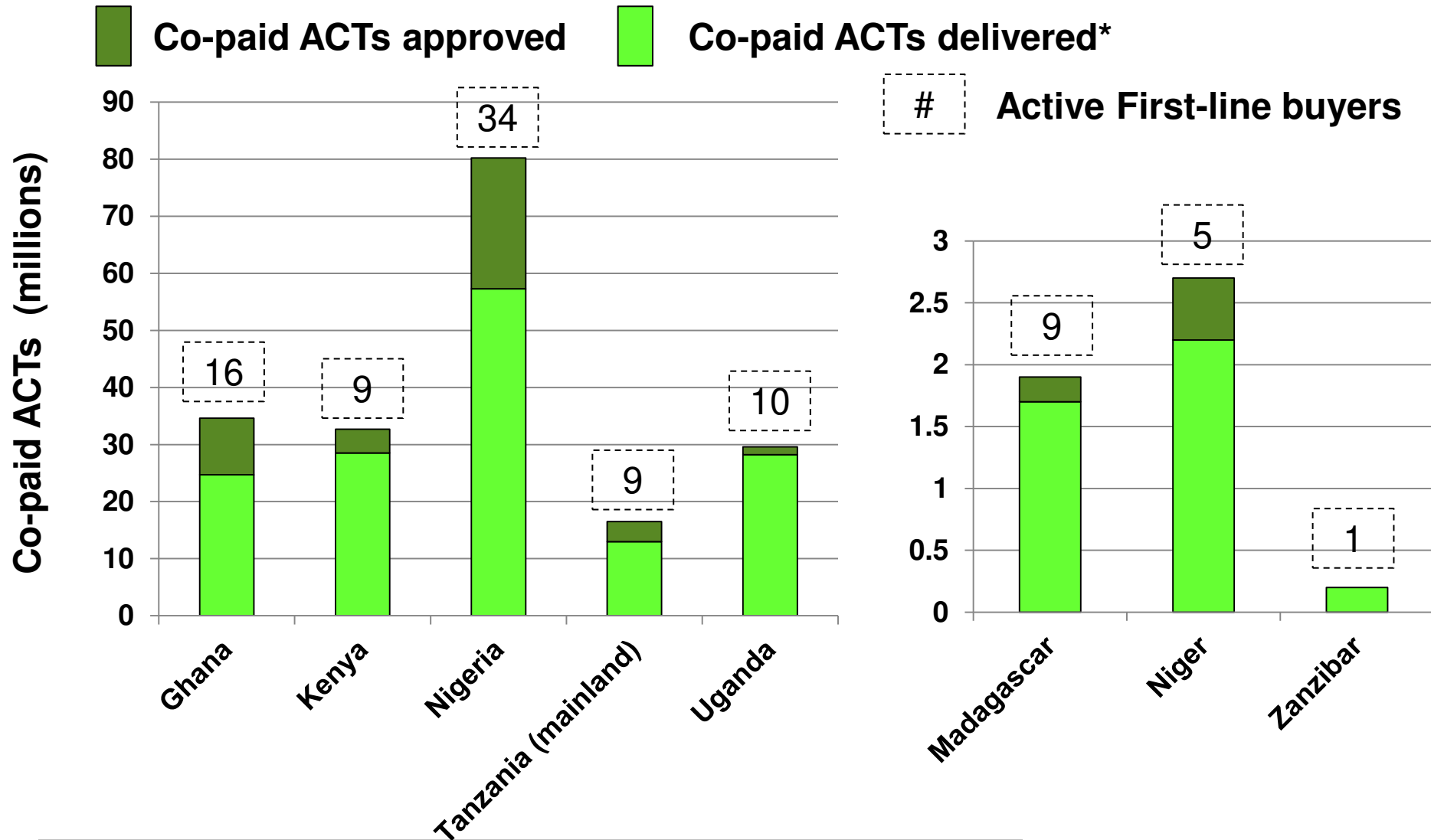
Within countries:

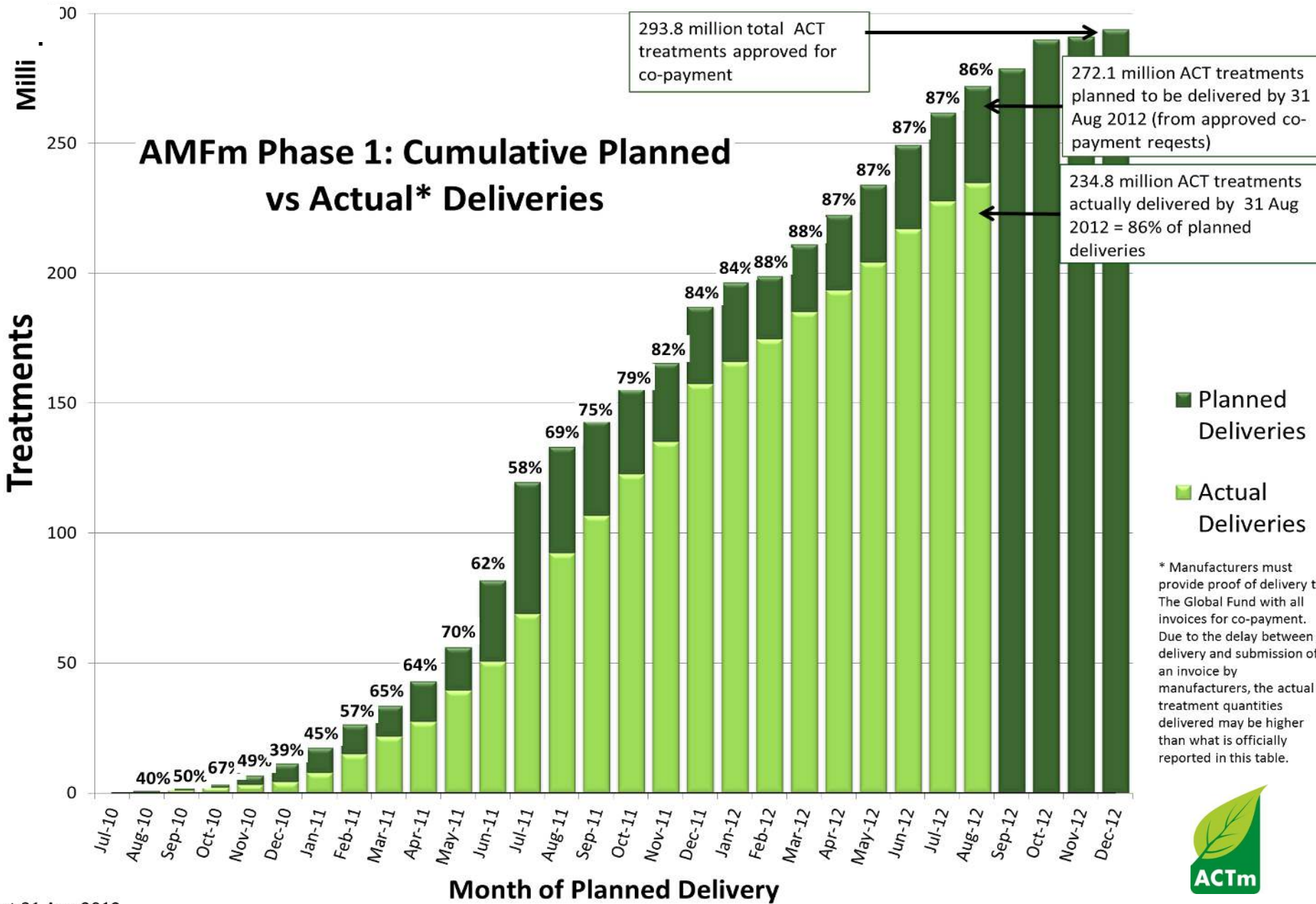
Some public sector entities (facility- and district-level) buy from private sector First Line Buyers to avoid stock-outs from delays in public sector/CMS procurement through imports

Examples: Ghana, Niger, Nigeria and Tanzania

Approved and Delivered ACT orders by pilot

[As of 31 Dec 2011]





As at 31 Aug 2012

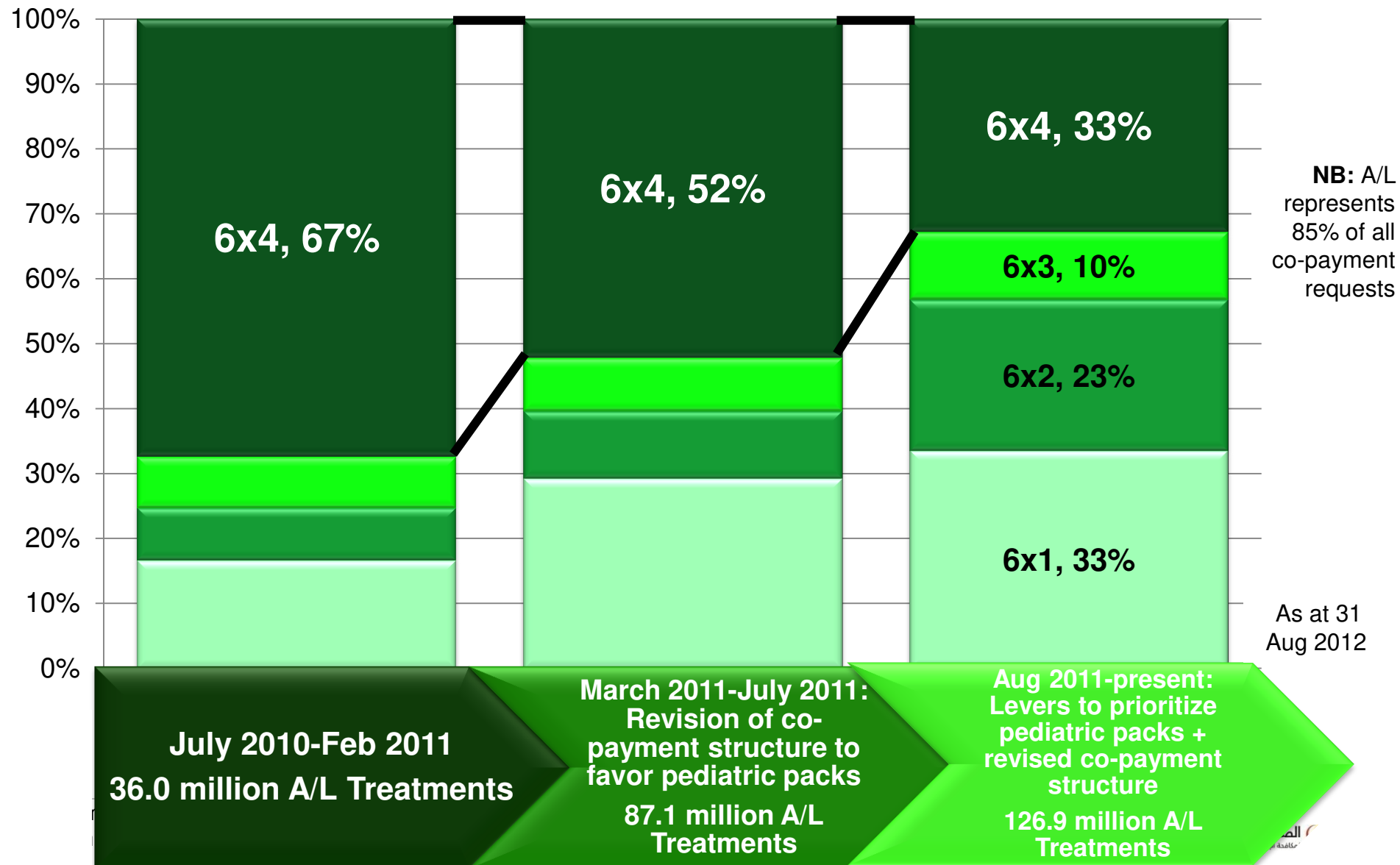
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Levers for managing orders

- Ratio of cumulative approved orders to estimated demand (using 2011 Quarter 1 estimates)
- Manufacturer performance (in terms of ratio of actual to planned deliveries by a particular date)
- First-line buyer pipeline
- Delivery date
- Formulation/pack size
- Mode of transport
- Sector
- FDCs preferred to co-blistered forms



A/L - Relative Percentage of Pack Sizes, pre- and post-revision of co-payment structure and introduction of levers



Some Phase 1 pilots affected by levers more than others

Quality-assured ACT treatments requested by private not-for-profit and private for-profit first-line buyers and approved by the Global Fund, Q3 and Q4 2011 only

AMFm Phase 1 Pilot	Quantity of quality-assured ACT treatments requested by first-line buyers	Quantity of quality-assured ACT treatments approved by the Global Fund	Proportion of quality-assured ACT treatments approved by the Global Fund
Ghana	28,084,120	7,699,920	27%
Kenya	7,263,320	4,071,000	56%
Madagascar	317,054	317,054	100%
Niger	575,140	575,140	100%
Nigeria	62,665,768	15,324,600	24%
Tanzania	4,772,200	4,272,200	90%
Uganda	5,183,880	2,953,880	57%
Zanzibar	0	0	--
Total	108,861,482	35,213,794	32%

Timeline of events: different for each pilot

- **Board approval to grant amendment:**
 - 6 months (Madagascar, Niger) to 16 months (Uganda)
- **Grant amendment to arrival in-country of co-paid ACTs:**
 - 1 month (Kenya) to 10 months (Niger)
- **Grant amendment to first disbursement for the implementation of supporting interventions:**
 - 1 month (Madagascar) to 9 months (Uganda)

Timeline of events



Timeline of AMFm Phase 1 Independent Evaluation data collection, grant amendments + disbursements, arrival in-country of co-paid ACTs		2010												2011					2012						
		A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M
Ghana	IE data collection (OS)																								
	X=grant amendment; \$=disbursement			X																					
	Co-paid ACTs in-country																								
Kenya	IE data collection (OS)																								
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Notes: **■** = IE data collection **X**=grant amendment; **\$**=disbursement **■** Co-paid ACTs in-country (although not necessarily in continuous supply over the entire period)
 **Nigeria: Baseline data collection completed Sept-Nov 2009. OS = Outlet survey (main study)