Unitaid
Innovation in Global Health

KEY PERFORMANCE INDICATORS

2016

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Acronyms and Abbreviations

3TC	Lamivudine
A2S2	Assured Artemisinin Supply Service
ABC	Abacavir, HIV/AIDS medicine
ACT	Artemisinin-based combination therapy for malaria
AFI	Areas for Intervention
AFRO	African Regional Office (WHO)
AIDS	Acquired Immune Deficiency Syndrome
AMRO	Regional Office of the Americas (WHO)
API	Active Pharmaceutical Ingredient
ART	Antiretroviral therapy for HIV/AIDS
ARV	Antiretrovirals for HIV/AIDS
BMGF	Bill and Melinda Gates Foundation
CD4	Cell differentiation 4
CHAI	Clinton Health Access Initiative
CS	Civil Society
CSO	Civil Society Organization
DAA	Direct-acting antivirals
DFID	Department for International Development
DNDi	Drugs for neglected diseases initiative
DRW	Diagnostics for the Real World
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EID	Early infant diagnosis
EOI	Expression of interest
ERP	Expert Review Panel
FDC	Fixed-dose combination
FEI	France Expertise Internationale
FIND	Foundation for Innovative New Diagnostics
FPP	Finished Pharmaceutical Product
GDF	Global Drug Facility of the Stop TB Partnership
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IBB	Institut Bouisson Bertrand
IPMA	Innovation in Paediatric Market Access
ISMO	Improving Severe Malaria Outcomes

ITPC	International Treatment Preparedness Coalition
IVD	In-Vitro Diagnostic
KPI	Key Performance Indicator
LIC	Low income countries
LLIN	Long-Lasting Insecticide-Treated Nets
LMIC	Lower-middle-income countries
LHSTM	London School of Hygiene & Tropical Medicine
MC	Malaria Consortium
MDR-TB	Multi-drug resistant TB
MIC	Middle Income Country
MMV	Medicines for Malaria Venture
MoU	Memorandum of Understanding
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NGOs	Non-governmental Organizations
PEPFAR	The United States President's Emergency Plan for AIDS Relief
POC	Point of care
PMI	President's Malaria Initiative
PQ	Prequalification Programme
PQR	Price & Quality Reporting (procurement database from GFATM)
PRC	Proposal Review Committee
PrEP	Pre-Exposure Prophylaxis
PSI	Population Services International
RDT	Rapid Diagnostic Test
SAMBA	Simple AMplification Based Assay
SEARO	South-East Asian Regional Office (WHO)
SMC	Seasonal Malaria Chemoprevention
SO	Strategic objective
SRS	Strategic Rotating Stockpile for MDR-TB medicines
TB	Tuberculosis
UMIC	Upper-middle-income countries
UN	United Nations
UNAIDS	The Joint United Nations Programme on HIV and AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Emergency Fund
UoL	University of Liverpool
USAID	United States Agency for International Development
VL	Viral Load
WB	World Bank
Wits RHI	Wits Reproductive Health Institute
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis

Introduction

Unitaid is an international organization that invests in new ways to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, more cheaply and more effectively. Unitaid is a hosted partnership of the World Health Organization (WHO).

Scope of this KPI report

Unitaid analyses performance against its Key Performance Indicators (KPIs), publishing a KPI report in June each year, based on results during the preceding calendar year. This report presents Unitaid's results for 2016, towards achieving the six strategic objectives outlined in Unitaid's Strategy for 2013-2016; thus it reflects organizational performance during the final year of the strategic period.

Unitaid had six strategic objectives for the period 2013-2016, which were:

1. SIMPLE, POINT OF CARE (POC) DIAGNOSTICS
   Increase access to simple, point of care (POC) diagnostics for HIV/AIDS, TB and malaria.

2. AFFORDABLE, ADAPTED PAEDIATRIC MEDICINE
   Increase access to affordable paediatric medicines to treat HIV/AIDS, TB and malaria.

3. TREATMENT OF HIV/AIDS AND CO-INFECTIONS
   Increase access to emerging medicines and/or regimens as well as new formulations, dosage forms or strengths of existing medicines that will improve the treatment of HIV/AIDS and co-infections such as viral hepatitis.

4. TREATMENT OF MALARIA
   Increase access to artemisinin-based combination therapies (ACTs) and emerging medicines, which in combination with appropriate diagnostic testing, will improve the treatment of malaria.

5. TREATMENT OF SECOND LINE TUBERCULOSIS
   Secure supply of second-line tuberculosis medicines and increase access to emerging medicines and regimens that will improve treatment of both drug-sensitive and MDR-TB.

6. PREVENTATIVES FOR HIV/AIDS, TB AND MALARIA
   Increase access to products for the prevention of HIV, TB and malaria, notably to improve the availability of devices for male circumcision and microbicides, once they are approved; and to increase access to vector control tools to prevent malaria transmission.

Summarizing Unitaid's performance over 2013-2016

As Unitaid enters a new strategic period over 2017-2021, it is worthwhile to reflect upon the organization's recent achievements.

Over the last strategic period 2013-2016, Unitaid has delivered some notable successes including accelerating the demand and adoption of two important malaria interventions, one to improve prevention during high transmission periods (Seasonal Malaria Chemoprevention), the other to treat severe malaria more efficiently and effectively (injectable artesunate). In both cases, these products are likely to reduce the overall burden of malaria, in particular in children under 5.

Unitaid's investments to support access to paediatric Antiretroviral (ARV) treatment and 2nd-line ARVs have delivered strong impact, with increasing numbers of countries procuring new treatment options which are optimally designed to the needs of different groups, such as dispersible paediatric formulations (44 countries procuring by 2016), and 2nd-line therapies with lower pill burdens (38 countries procuring by 2016).

Moreover, Unitaid has expanded scope to make investments into Hepatitis C (as a HIV co-infection), has increased investment into point-of-care HIV testing, notably in the area of Early Infant Diagnosis of HIV, HIV Self Testing and PrEP; all of which are intended to accelerate the demand and adoption of innovative health products and approaches to support meeting the 90-90-90 goals for HIV/AIDS.

In respect of Tuberculosis (TB), significant outcomes were delivered in securing the availability of a quality-assured paediatric treatment, optimally designed for children (through the STEP TB project). Another critical issue which Unitaid has invested in tackling is TB diagnosis. Through improving the affordability of, and subsequently increasing access to, GeneXpert, health systems can potentially provide more rapid TB diagnosis at lower

levels of the health system, more efficiently; benefiting from the faster test turnaround time of GeneXpert. Over the long-term, it is anticipated that Unitaid's investment in paediatric TB and TB diagnosis will play an important role in reaching the global goals for tuberculosis.

Cross-cutting investments into WHO pre-qualification (PQ) and the Medicines Patent Pool (MPP) have also delivered tangible results, with the PQ programme pre-qualifying over 110 medicines across HIV/AIDS, TB and malaria, and almost 50 in-vitro diagnostics over the last four years. The MPP has increased access to affordable HIV medicines, and is estimated to have saved the global response more than US$ 300m to date, with this figure expected to increase further over time, increasing the overall efficiency of the HIV/AIDS response.

As Unitaid moves into a new strategic period, it also takes note of important lessons learned during 2013-2016. The most critical of these is the need for increased focus on the transition and scale-up of Unitaid-supported products and approaches, both within and beyond project countries. Supporting this, to ultimately deliver impact at scale, it is critical to define, approve, monitor and evaluate investments underpinned by a sound Theory of Change, fit-for-purpose log frame, and clear operational plan. Stronger planning can minimize delays in implementation, improve project delivery and increase focus on the transition and scale-up of Unitaid's investments, to ultimately deliver a more effective global response.

Other highlights from 2016

Over the past two years, Unitaid has transformed its operating model. The design phase of this new model started in January 2015, based on the findings of a functional review conducted in late 2014. Implementation of the new operating model started in June 2015. Further initiatives linked to this effort occurred in 2016 including the development of a new Unitaid Strategy for 2017-2021, supplemented by finalization of an up-to-date Risk management framework and the creation of a Value for Money framework; organizational reforms have also been supported by a change management approach. The new Strategy is supplemented by a new set of KPIs. Both the Strategy and KPIs were approved by the Unitaid Executive Board in December 2016. More detail on the new KPI framework can be found in the section "Looking forward – Key Performance Indicators for 2017-2021", below. The new KPIs will be reported upon for the first time in June 2018 (based on 2017 performance).

KPI 1

Monitoring Performance Towards Public Health Outcomes

Unitaid's investments are ultimately focused on delivering tangible public health outcomes at scale across HIV/AIDS (including Hepatitis C co-infection), TB and malaria. KPI 1, "**Monitoring performance towards public health outcomes**" has four sub-indicators:

1.1	**Per cent coverage of Unitaid-supported products by strategic objective**
1.2	**Number of people on treatment/tested for HIV, TB and malaria by strategic objective**
1.3	**Per cent of grant public-health targets achieved as per grant agreements**
1.4	**Per cent of Unitaid investments covering high-burden countries**

1.1. Per cent coverage of Unitaid-supported products by strategic objective

KPI 1.1 measures the level of coverage of products supplied by Unitaid in 2016. As a catalytic organization, Unitaid projects typically do not test and treat large numbers of people living with a disease. Thus, the level of coverage resulting from a Unitaid investment is normally relatively low during implementation. However, coverage of the product is expected to reach much higher levels after scale-up through countries and other funding partners, such as the Global Fund, PEPFAR and PMI.

The results presented partially reflect the evolution of the portfolio over the 2013-2016 strategic period, moving away from a series of large-scale, procurement related investments in the areas of paediatric and second-line ARVs, and Artemisinin-based Combination Therapy (ACT) to investments intended to support the demand and adoption of point-of-care HIV testing and monitoring, access to Hepatitis C treatment, and next-generation Indoor Residual Spray (IRS). Table 1.1 below summarizes the coverage levels of products supported by Unitaid in 2016.

Data from multiple projects are combined to calculate coverage levels for Strategic Objective 1: point-of-care tests (for HIV only). In all other

cases, the coverage level reflects a stand-alone project, e.g. Seasonal Malaria Chemoprevention for Strategic Objective 6.

As with other years in the strategic period, the results show a range coverage levels per project, with some investments having coverage levels of less than 1 per cent (for access to treatments for HCV), up to significantly higher levels for larger-scale delivery-related investments such as the ACCESS SMC project for Seasonal Malaria Chemoprevention. Most Unitaid project coverage levels are below 10 per cent, reflecting the catalytic nature of the portfolio.

Results 1.1 Per cent coverage of Unitaid-supported products by strategic objective

SO	Disease	Description	Numerator	Denominator	Coverage
SO1: Simple, point of care tests for HIV, TB and malaria	**HIV**	Simple Point-Of-Care (POC) early infant diagnostic (EID) tests that can be done at point of care	Number of POC EID tests available through Unitaid support	Estimated number of pregnant women living with HIV in 2015 in project countries	2.8%
		POC Viral load (VL) tests that can measure patient response to ARVs without need to referral to a central hospital	Number of POC VL tests available through Unitaid support	Estimated number of people on treatment in 2016 (assuming the need for 2 viral load tests for each to monitor treatment) in project countries	2.0%
		POC CD4 tests that can measure patient response to ARVs without need to referral to a central hospital	Number of POC CD4 tests available through Unitaid support	Estimated number of people on treatment in 2016 (assuming the need for 2 CD4 tests for each to monitor treatment) in project countries	3.7%
	TB	Rapid tests to detect and treat Multi-Drug Resistant TB (MDR-TB)	Number of MDR-TB and rifampicin resistance cases detected through Unitaid support	Estimated number of people who developed MDR-TB in 2015 in project countries	8.6%
SO3: Increase access to treatments for HIV and co-infections	**HIV**	New medicines for Hepatitis C Virus (HCV) (the DAAs)	Number of treatment courses that include new DAAs through Unitaid support	Estimated number of co-infected people in need of HCV treatment in project countries	0.2%
SO4: Access to artemisinin-based combination therapies (ACTs) and emerging medicines	**Malaria**	Injectable artesunate, a safer alternative to quinine, is used to treat severe malaria patients	Number of injectable artesunate treatment courses procured in 2016 through Unitaid support	Estimated incidence of severe malaria according to latest available estimates from WHO in project countries	19.5%
SO5: Secure supply of second-line tuberculosis medicines and increase access to emerging medicines for MDR-TB	**TB**	Better medicines are needed to improve the cure rate of treatment for Drug Resistant TB (DR-TB)	Number of people being treated for drug-resistant TB with a regimen that includes either bedaquiline or delamanid through Unitaid support	Estimated number of people starting treatment for DR-TB in 2016 in project countries	2.9%
SO6: Increase access to products for prevention of HIV, TB and Malaria	**Malaria**	New care delivery models are needed to implement Seasonal Malaria Chemoprevention (SMC) in recommended countries	Number of SMC treatments (SP+AQ) administered to eligible children in 2016 through Unitaid support	Estimated number of (SP+AQ) treatments needed by eligible children in Sahel project countries	47.4%
SO6: Increase access to products for prevention of HIV, TB and Malaria	**Malaria**	Malaria prevention in children by utilizing existing technology	Number of people protected by Indoor Residual Spray (IRS) through Unitaid support	Estimated number of people in malaria endemic areas with pyrethroid resistance in project countries	34.6%
SO6: Increase access to products for prevention of HIV, TB and Malaria	**HIV**	To help in meeting UNAIDS target that 90 percent of PLHIV should know their status by 2020	Number HIV Self Tests procured through Unitaid support	Estimated number of people likely to be reached by HIV Self Tests in project countries	7.8%

1.2. Number of people on treatment/ tested for HIV, TB and malaria by strategic objective

KPI 1.2 measures the number of people on treatment/tested for HIV (and related co-infections), TB and malaria by strategic objective, as a result of Unitaid investment in 2016. As with previous years over the strategic period, the numbers reported here (Table 1.2, below) vary across projects and represent a measure of the direct effect of Unitaid's investments across different projects; reflecting relatively low numbers in most cases, following the same logic as outlined for KPI 1.1. These numbers reflect the numerators used to calculate KPI 1.1, with one exception for HIV Self-Testing. Here, it is difficult to calculate precisely how many people tested for HIV, as Self-Testing should be followed up by confirmatory testing. Therefore, it is excluded from this analysis.

The number of people on treatment/tested for HIV (and related co-infections), TB and malaria within Unitaid projects ranged from less than 1,000 people (within a clinical development project - ENDTB) to over 6.9 million people (within a larger-scale delivery project – ACCESS SMC). The smaller figures typically reflect projects that are operating at a small, pilot-level scale.

Results 1.2 Number of people on treatment/tested for HIV, TB and malaria by strategic objective

SO1	Number tested- CD4	207,000
SO1	Number tested- EID	27,000
SO1	Number tested- Viral Load	112,000
SO1	# TB cases detected with Xpert	84,000
SO1	Number of treatment courses that include new DAAs	850
SO3	Adults switched to 2nd-line ARVs after testing	1,500
SO4	Number of injectable artesunate treatment courses delivered	185,000
SO5	Number of people being treated for drug-resistant TB with a regimen that includes either bedaquiline or delamanid	760
SO6	Number of children reached with Seasonal Malaria Chemoprevention	6,900,000

1.3. Per cent of grant public health targets achieved as per grant agreements

Across Unitaid's portfolio, there are a range of public health targets set within the logical framework of relevant projects. KPI 1.3, per cent of grant public health targets achieved as per grant agreements, captures performance against these targets, normally measured at the point of project closure. Over 2016, five projects closed, out of which three projects had public health targets.

Across the three projects, there are six public health targets overall. In the case of the Improving Severe Malaria Outcomes (ISMO) project, the public health target was exceeded (increased proportion of severe malaria cases treated with Injectable artesunate vs Quinine)). For the PSI-RDT project, one target was exceeded and one target was almost met (i.e. a result of 87 per cent for the proportion of patients (all age) seeking fever treatment through targeted private sector outlets received an RDT test, against a target of 88 per cent). Finally, for the TBXpert project, the target for incident TB cases detected using project commodities was exceeded, whilst the other two targets (number of HIV-positive TB patients detected using project commodities and number of incident rifampicin-resistant TB patients detected using project commodities) were both slightly under target at 83 per cent and 88 per cent respectively. However, Unitaid's framework for evaluating performance denotes that reaching 80 per cent of the target is considered as achieving public health targets.

Therefore, 100 per cent of the projects closed in 2016 met their public health targets overall, which is broadly consistent with the performance against this KPI over the strategic period.

Results 1.3 Per cent of grant public health targets achieved as per grant agreements

Project	Indicator	Target	Results	%
ISMO	Proportion of severe malaria cases treated with Injectable Artesunate versus quinine	85%	86%	>100%
PSI-RDTs	Proportion of patients (all ages) seeking fever treatment through targeted private-sector outlets received an RDT test	88%	87%	99%
	Proportion of patients testing positive for malaria at targeted private-sector outlets that receive an effective antimalarial treatment	30%	74%	>100%
WHO TBXpert	Number of incident TB patients detected using project commodities	233,213	244,983	>100%
	Number of incident HIV-positive TB patients detected using project commodities	25,955	21,546	83%
	Number of incident rifampicin-resistant TB patients detected using project commodities	60,937	53,794	88%

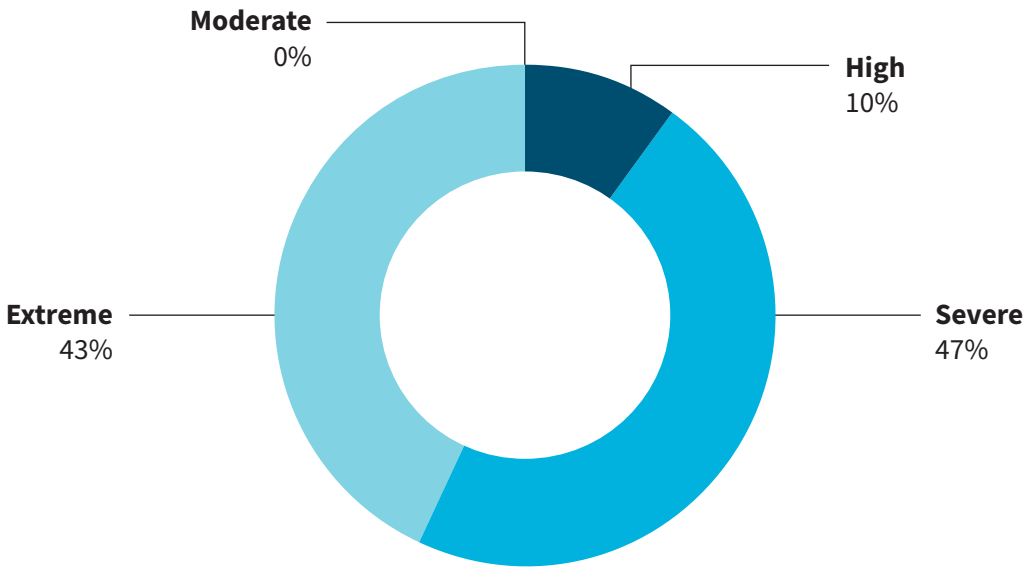
1.4. Per cent of Unitaid investments covering high burden countries

Unitaid's investments are intended to catalyze equitable access to better health products and approaches. On this basis, these investments are designed to benefit the poorest and the underserved (across diseases). KPI 1.4 assesses the extent to which Unitaid's investments are focused towards countries with the greatest needs, on the basis of disease burden. As with previous years, for consistency with other partners, we use the Global Fund definition of disease burden.

The 2016 results (see Figure 1, below) shows that 99 per cent of investments remain focused in countries with high, severe or extreme burden in one or more of the three diseases; less than 1 per cent of all investments were in the moderate category. Compared to previous years, the 2016 results have a greater proportion of investment within the extreme disease burden category (43 per cent this year, compared to 33 per cent in 2015). The investments are measured by the actual procurement of commodities under active grants, at the country level.

FIGURE 1.

Investment by disease burden*



* https://www.theglobalfund.org/media/5597/core_eligiblecountries2016_list_en.pdf

KPI 2

Monitoring Performance Towards Market Outcomes

KPI 2, "**Monitoring performance towards market outcomes**" covers the following sub-indicators:

2.1	**Number of products entering the market with Unitaid-support by strategic objective**
2.2	**Per cent price reduction of Unitaid supported products by strategic objective a) over grant life or b) 3 years after grant closure, where applicable**
2.3	**Number of countries procuring at or below a price obtained by Unitaid a) over grant life or b) 3 years after grant closure**
2.4	**Per cent of grant achieving market targets as outlined in their grant agreements**

2.1. Number of products entering the market with Unitaid support by strategic objective

Unitaid supports the expansion of access to quality-assured products (for both existing products and newly available products) through an investment in the WHO Prequalification Programme (PQ) for medicines and diagnostics ("PQ medicines" and "PQ diagnostics"). KPI 2.1 measures the annual performance of this investment.

Unitaid's support to the PQ programme is intended to catalyse the introduction of urgently needed medicines and diagnostic products in low- and middle-income countries that have limited regulatory capacity. The 2016 results show that 28 Finished Pharmaceutical Products (FPPs), 11 Active Pharmaceutical Ingredients (APIs) and 12 In- Vitro Diagnostics (IVDs) corresponding to Unitaid's areas of focus were prequalified and available for procurement by international procurers and funders. The full list of prequalified products is available in Annex 2.

Results 2.1 Number of products corresponding to priority disease areas entering the market with Unitaid support

	Diseases	Medicines	Diagnostics	
		FPPS	**APIS**	**IVDS**
Unitaid Priority diseases	HIV	14	2	11
	HCV	2	0	1
	TB	12	7	0
	Malaria	0	2	0
TOTALS		28	11	12

2.2. Per cent price reduction of Unitaid-supported products by strategic objective a) over grant life or b) 3 years after grant closure, where available/ applicable

Product price reductions are an important element of securing the affordability of innovative health products. KPI 2.2 measures the change in price of products supported by Unitaid through its investments. Reductions have been achieved through different mechanisms including negotiating long-term agreements, increasing procurement volumes or securing market access for generic manufacturers.

KPI 2.2 measures price reductions over the project life (collected through the project and from other external sources) and up to 3 years beyond project closure. After project closure, price information is captured from publicly available procurement data. Overall 6 of 11 products have seen a price reduction in 2016, based on a comparison of the 2016 price with the first price recorded during the project, e.g. across three HIV point-of-care tests, a Hepatitis C treatment, and injectable artesunate. Despite increasing demand for injectable artesunate, delays in new suppliers entering the market have caused prices to fluctuate. Overall, price reductions have ranged from 2 to 34 per cent. Finally, 3 of 11 products saw no change in price, and 2 of 11 products saw a small increase in price of around 1-2 per cent from the original price recorded.

Results 2.2 Percentage price reduction of Unitaid-supported products

	Unit	2013 Price per unit US$	2014 Price per unit US$	2015 Price per unit US$	2016 Price per unit US$	Change in price
Xpert HIV-1 Viral Load	one test	-	-	19.1	16.80	-12%
Xpert HIV-1 Qual (EID)	one test	-	-	19.9	17.95	-10%
AlereQ HIV 1/2 Detect	one test	-	-	25	25	0%
PIMA PoC CD4 cartridge	one test	5.95	5.95	5.95	5.95	0%
BD FACSPresto	one test	-	9	8.8	7.50	-16%
Oraquick HCV Rapid Antibody test	one test	-	-	8.4	8.60	+2%
SAMBA I cartridge	one test	-	44	-	44.6	+1%
Xpert MTB/RIF cartridge	one test	9.98	9.98	9.98	9.98	0%
Sofosbuvir (400 mg)	per tablet	-	-	10.1	6.65	-34%
Artesunate 60 mg Injection	per vial	-	1.59	1.5	1.56	-2%
Artemether/ Lumefantrine (20/120 mg) (pack size 6x4)	ACT FDC treatment course (adult >35 kg)	0.46-2.17 (1.31 average)	n/a	1.0	1.1	-16%

* The price and quality database of the Global Fund accessed 05 May 2017

2.3. Number of countries procuring at or below Unitaid obtained price a) over grant life or b) 3 years after grant closure

KPI 2.3 measures how broadly Unitaid-supported products can be procured at or below the Unitaid-obtained price, over the life of a project and up to 3 years beyond project closure. For 2016, the results include data from (i) results reported by implementing partners, and (ii) other procurement data, e.g. from the Global Fund and PEPFAR.

The 2016 results show that, of the 9 products supported under the active grants with available data, 2 products were not reported in previous years (Actellic – 4 countries, and Artemether/Lumefantrine – 18 countries). Of the remaining 7 products included in last year's analysis, 6 of 7 products have seen an increase in the number of countries procuring at or below the Unitaid obtained price.

Results 2.3 Number of countries procuring at or below Unitaid obtained price a) over grant life or b) 3 years after grant closure

Disease	Product	Last Unitaid price per patient per treatment/ test (US $)	Number of countries 2016
HIV	Xpert HIV-1 Viral Load Cartridge	16.8	9 (up from 3 in 2015)
HIV	Xpert HIV-1 Qual (EID) Cartridge	17.95	5 (up from 2 in 2015)
HIV	PIMA PoC CD4 cartridge	5.95	20 (up from 7 in 2015)
HIV	BD FACSPresto cartridge	7.5	2 (down from 4 in 2015)
TB	Xpert MTB/RIF cartridge	9.98	130 (up from 121 in 2015)
HCV	Sofosbuvir (400 mg)	6.65	3 (up from 1 in 2015)
Malaria	Artesunate 60 mg Injection	1.56	11 (up from 6 in 2015)
Malaria	Actellic 3GIRS	23.5	4 (not reported in 2015)
Malaria	Artemether/Lumefantrine (20/120 mg) (pack size 6x4)	1.10	18 (not reported in 2015)

2.4. Per cent of grants achieving their market targets as outlined in their grant agreements

Unitaid measures the achievement of market-related targets for projects that closed in 2016. Over 2016, each of the projects that closed had at least one market-related target, with 8 targets in total. Table 2.4 below summarises the results. Of 8 targets overall, 3 were fully met, which is broadly consistent with performance over the 2013-2016 period.

Focusing on where some targets were not met, e.g. within the IPMA project, two-thirds of all paediatric ARVs in scope of the project (13 of 20 products) secured at least two manufacturers with Stringent Regulatory Authority (SRA) or PQ status, which, despite not meeting the original target of more than two SRA or PQ manufacturers for every product, represents a significant increase in the manufacturer base for quality-assured paediatric ARVs.

In respect of ISMO, the price target for injectable artesunate was not met, driven mainly by the lack of market competition in 2016. However, the current price level for injectable artesunate does not adversely impact the cost-effectiveness and affordability of injectable artesunate. It is anticipated that in the near future additional suppliers will enter the market, which could lead to increased price competition. Furthermore, this project met targets for dossier submissions to WHO prequalification for two rectal artesunate products.

Finally, the STEP-TB project secured one manufacturer submitting a WHO PQ dossier, as opposed to a target of two manufacturers. However, the new fixed dose combination (FDC) has already proven popular with the WHO reporting in late 2016 that almost 30 countries had started procuring the FDC, with the number of countries procuring expected to rise further*.

Results 2.4 Per cent of grant market targets achieved as per grant agreements

Grant	Description	Target	Result	Performance
CHAI-IPMA	1. # of SRA/ PQ manufacturers offering optimal paediatric ARVs.	At least 2 per product	Target met for 13 out of 20 products	65%
	2. # of DBS bundle suppliers.	2	6	>100%
ISMO	Generic Inj AS dossier submitted for WHO Prequalification	1	1	100%
	Percentage reduction in median price of PQ Inj AS	1.20	1.56	-30%
ISMO	Generic RAS dossier submitted for WHO Prequalification	2	2	100%
PSI-RDTs	Percentage of targeted private sector outlets in project areas with quality-assured RDT brands in stock	60%	54%	90%
STEP-TB	Number of manufacturer submitting dossier to the WHO PQ and/or SRA for approval of a paediatric formulation	2	1	50%
WHO-Xpert	Rate of procurement of Xpert MTB/RIF cartridges in the public sector at concessional prices in 124 eligible countries (excluding TBXpert beneficiary countries)	1.3	1.1	85%

- PEPFAR database and Global Fund price and quality reporting database accessed 1 May 2017.
- World Health Organization. WHO monitoring of Xpert MTB/RIF roll-out: Procurement of GeneXpert and Xpert MTB/ RIF cartridges. [Cited 17 May 2016]. Available from: http://apps.who.int/tb/laboratory/xpertmap/.
- World Health Organization. – website, accessed 19 June 2017 http://www.who.int/tb/areas-of-work/children/en/

KPI 3

Accessibility of Market Information

Unitaid proactively screens the global-health market and identifies needs, challenges and opportunities for investments to improve health outcomes for the three diseases, and relevant co-infections. KPI 3 measures the extent to which there is "**Accessibility of market information**" to inform strategic decisions by Unitaid and partners, and is split into two sub-indicators.

3.1	**Per cent of new proposals that correspond to opportunities identified in the landscape reports/market fora annually**
3.2	**Per cent of Unitaid priority products for which price and supplier information is held in Unitaid's market intelligence information system**

3.1. Per cent of new proposals that correspond to opportunities identified in the landscape reports/ market fora annually

As a result of reforms agreed in June 2015, the Unitaid Executive Board now endorses "Areas for Intervention" (AfIs) as the core mechanism to launch Calls for Proposals which leads to investment into projects. These AfIs build upon analysis developed within Unitaid Market Landscapes and Disease Narratives, which help to pinpoint the most promising areas for Unitaid to make investments.

During 2016, five AfIs were endorsed by the Executive Board:

1. Better, shorter treatments for MDR-TB – March 2016
2. Scale-up of better tuberculosis treatment for children – March 2016
3. Enabling preventive tuberculosis treatment in high-risk groups – March 2016

4. Expanding access to HIV self-testing in LMICs – December 2016

5. Supporting the use of TRIPS flexibilities – December 2016

All AfIs reflect the agreed priorities of Unitaid, and follow targeted market analysis, extensive partner consultations, and the ultimate approval of the Executive Board as valuable areas to launch calls for proposals. These efforts require an intense investment of Secretariat time and resources, and have been welcomed by all partners, with partners' feedback and input resulting in greater clarity and value of potential Unitaid investments. Therefore, 100 per cent of all new proposals that moved into grant agreement development correspond to opportunities identified.

3.2.
Per cent of Unitaid priority products for which price and supplier information is held in Unitaid's market intelligence information system

Unitaid monitors prices paid by countries and donors for priority products through its internal database, which includes key market parameters on health products ranging from trends, volumes, countries and suppliers. Some KPIs in this report are based on this data. The database currently captures over 1,000 unique priority products (medicines and diagnostics), and close to $9 billion in commodity purchases over the last ten years.

In collaboration with the Global Fund, Unitaid is also co-funding wambo.org, a global marketplace which offers a range of quality-assured, lifesaving medicines and health-related commodities at competitive prices that are publicly available to buyers.

KPI 4

Accessibility of Market Information

KPI 4: "**Monitoring Grant Management**" covers a number of indicators related to how Unitaid is managing its investments.

This includes split of investments across a range of categories covering the 2013-2016 strategic objectives, disease areas, product types and lead grantee (KPI 4.1). Furthermore, KPI 4.2 measures the overall satisfaction of implementing partners with Unitaid's grant management processes, which is measured through a survey. KPI 4.3 measures the percentage of projects that receive some form of extension (no-cost or costed) each year. This is a proxy measure of project efficiency. Finally, KPI 4.4 measures the length of time taken from an Executive Board approval to develop a grant to the point of grant signature. Looking ahead, Unitaid's 2017-2021 KPIs will measure this differently, from the point of time of grant agreement development (GAD) kick-off, to the submission of a grant package to the Executive Board.

4.1	**Per cent of total investment by strategic objective and by disease, product type and lead grantee annually**
4.2	**Grantee satisfaction with grant related processes (based on annual survey)**
4.3	**Per cent of grants receiving extensions annually**
4.4	**Median number of days from Board approval to grant signature**

4.1.
Per cent of total investment by strategic objective and by disease, product type and lead grantee annually

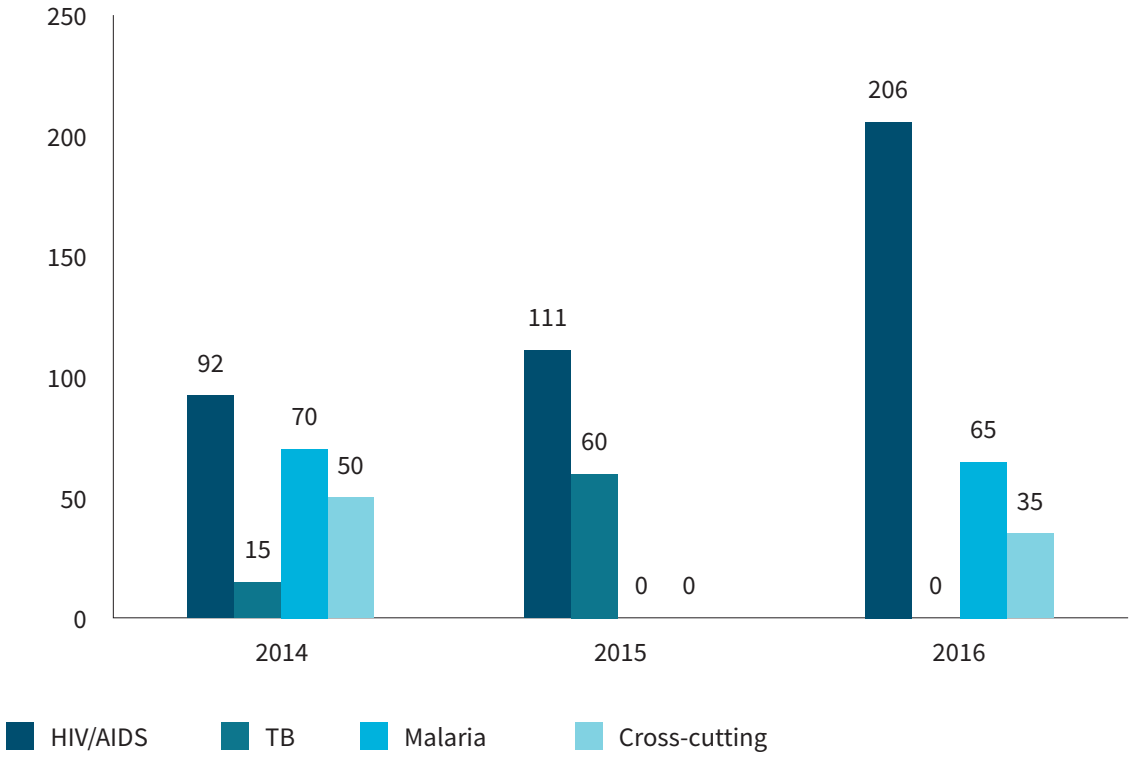
In 2015, investments were based on strategic objectives outlined in the 2013-2016 Unitaid Strategy. However, in 2016, the changes to the operating model were fully integrated and projects approved in 2016 reflected the approved Areas for Intervention, as opposed to a specific strategic objective. Therefore, the annual investment by strategic objective is not presented in this report.

However, an analysis of per cent of total investment in 2016, based on disease area and product type are illustrated in Figures 2 and 3 below. The majority of new investments in 2016 were in the HIV/AIDS disease area, with two-thirds of new investments, by grant agreement value, being channelled into this category (approximately US$ 206m). A further one-fifth of 2016 investment went to malaria (for one project – IVCC, US$ 65m), and just over 10 per cent into cross-cutting investments (US$ 35m). No investments were made into the TB portfolio in 2016. However, three AfIs in the TB area were agreed in 2016, which are anticipated to lead to investment into TB in 2017.

In terms of the split of the total portfolio by disease (based on grant agreement values), HIV/AIDS reflects around 53 per cent of the total portfolio as at 31 December 2016 (US$ 450m), malaria around one-quarter of the portfolio (US$ 213m), TB 12 per cent of the portfolio (US$ 103m) and cross-cutting investments just over 10 percent of the total portfolio (US$ 102m). As noted above, new investments are expected in the TB disease area to replenish this part of the portfolio in the near future.

FIGURE 2.

Grant agreement values (US$ m) by disease area



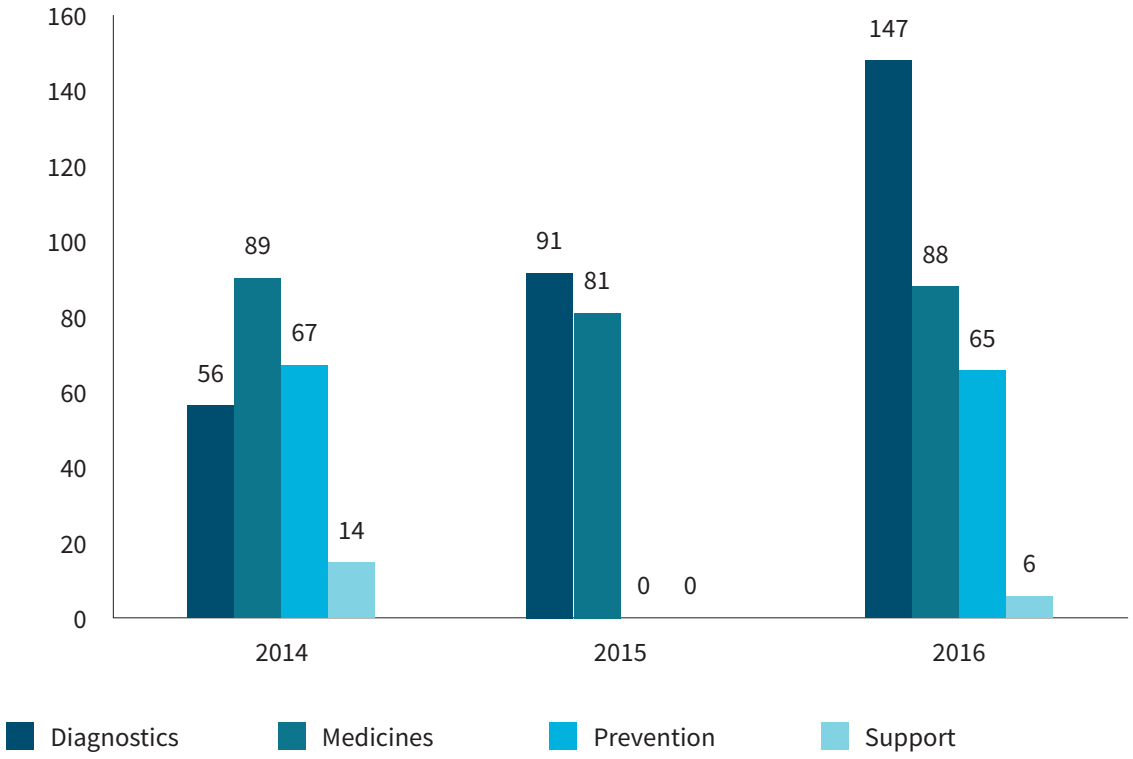
Breakdown of investments based on disease area in 2016, compared to previous years

In terms of portfolio split by product type, Figure 3 below shows that diagnostics cover the biggest share of our new investments in 2016 at US$ 147m in total (48 per cent). This was followed by medicines and prevention, at US$ 88m (29 per cent) and US$ 65m (21 per cent) of the portfolio, respectively. Cross-cutting grants that support disease-specific grants made up less than 2 per cent of our investments, at US$ 6m.

In terms of the split of the total portfolio by product type, diagnostics reflect around 40 per cent of the total portfolio as of 31 December 2016 (US$ 348m), medicines around one-third of the portfolio (US$ 281m), prevention around 22 per cent of the portfolio (US$ 194m) and support investments just under 4 per cent of the total portfolio (US$ 34m).

FIGURE 3.

Grant agreement values (US $m) by product type



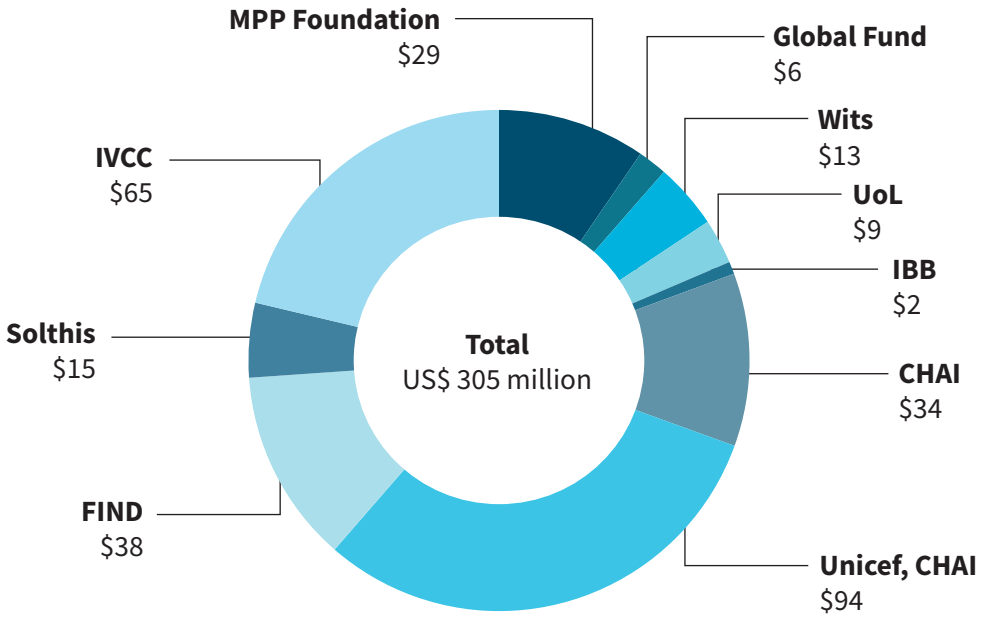
Breakdown of investments based on product type in 2016, compared to previous years

A list of lead grantees for active projects in 2016 can be found at Annex 1. In summary, the pool of lead grantees expanded in 2016 to include new implementing partners for Unitaid, including a range of academic institutes delivering clinical development projects under the Optimal ARV AfI, such as the University of Liverpool. A number of well-established implementing partners, such as CHAI, FIND and PSI, also continue to deliver multiple projects funded by Unitaid.

Ten new projects started implementation in 2016 (with a number of additional projects approved in 2016 which will start to deliver activities in 2017). The biggest share of 2016 investment was allocated to the CHAI/UNICEF project on point of care diagnostics, phase 2b, which is a US$ 94m investment. One fifth of all new investments made in 2016 were committed to IVCC, a US$ 65m investment. The range of investment was approximately US$ 2m to US$ 94m.

FIGURE 4.

Allocation of funds in 2016, based on new lead grantee, in US$ millions

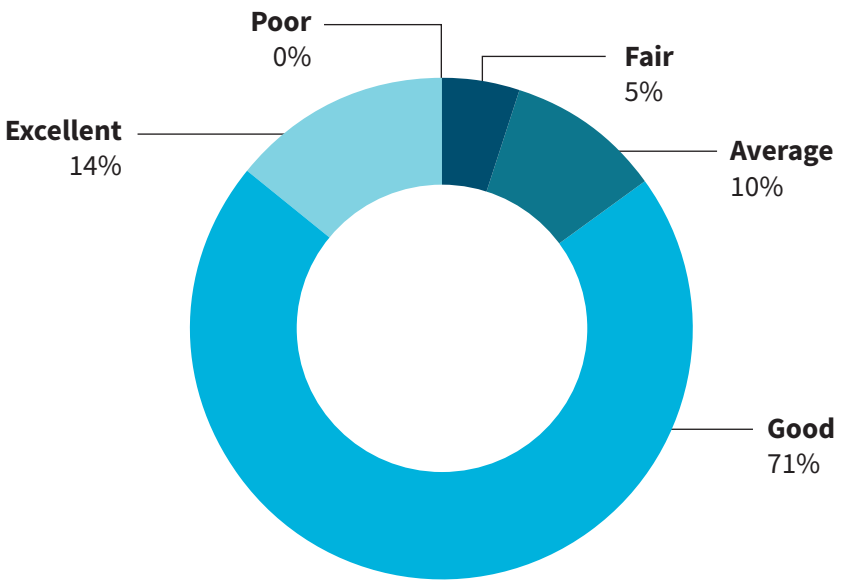


4.2. Grantee satisfaction with grant related processes (based on annual survey)

Grantee satisfaction is an important indicator of grant management for Unitaid. In a survey conducted in 2016, 85 per cent of our grantees expressed satisfaction (rated as Good or Excellent) with grant processes, based on the question "How would you rate your overall experience with Unitaid?" No grantee rated this indicator as "Poor".

FIGURE 5.

Grantee Satisfaction



Reported grantee satisfaction in survey conducted

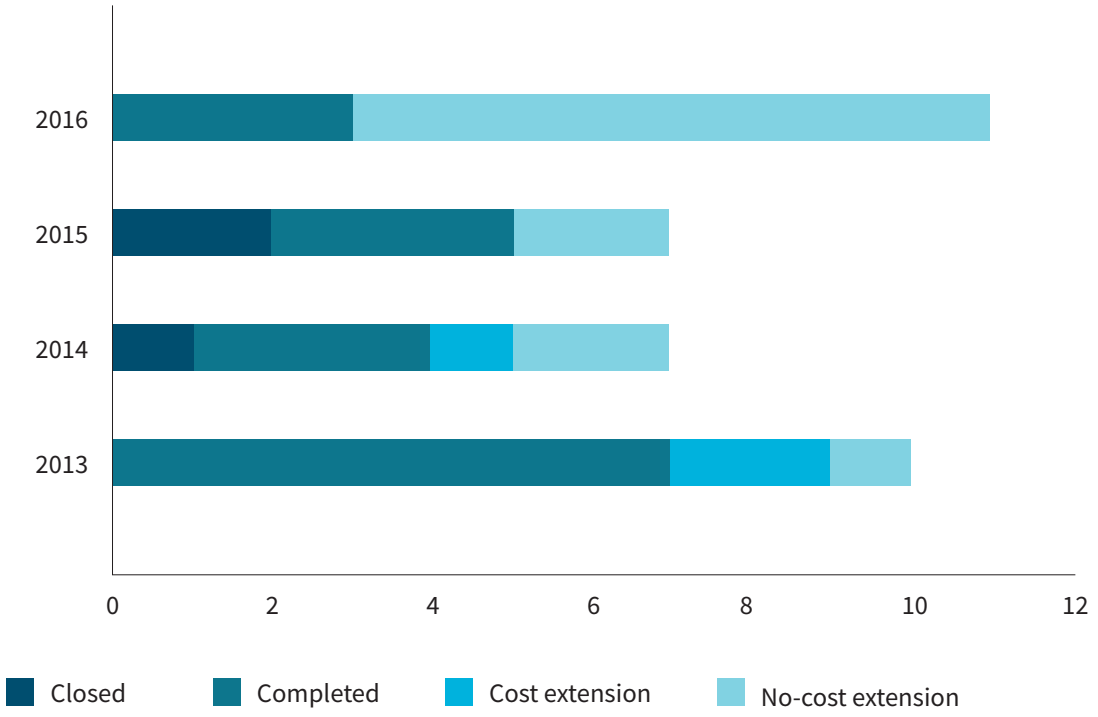
4.3. Per cent of grants receiving extensions annually

Unitaid investments are time-limited, catalytic interventions that address a range of market barriers to ultimately provide better health products and approaches at scale through other funding sources. These investments are inherently risky; working on catalyzing access to innovative products, typically in resource-poor settings means that some projects can suffer unforeseen delays. In some cases, there is value in extending the duration of the project (with or without cost) to deliver critical activities. Some projects can also be given short time extensions, which are not considered as formal project extensions, to undertake final reporting and to close budgets etc.

Eight projects received an extension in 2016, and three were completed. Two projects receiving an extension were bridging into a new phase of the project, which was underpinned by an entirely new project plan, logframe and budget (OPP-ERA and CHAI/UNICEF). In 2016, all approved extensions were no-cost extensions.

FIGURE 6.

Number of grants receiving an extension in 2013-2016



4.4. Median number of days from Board approval to grant signature

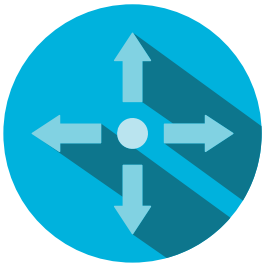
Seven projects were signed in 2016 which were designed using the new Grant Agreement Development (GAD) approach (six of which started implementation in 2016, with University of New South Wales starting in early 2017). A number of other projects were also signed in 2016, including the IVCC project and CHAI/UNICEF Phase 2b, which were under development prior to the introduction of the GAD processes in early 2016.

Based on the GAD projects, the median number of days from "Go- ahead" to grant signature was 209 days (average 202 days). This approach differs to the one employed under the previous operating model, e.g. where the Go-ahead is based on a proposal which has already been rigorously reviewed, and involves a number of stages of grant development, before final submission to the Executive Board for approval. Therefore, the results of this KPI for 2016 are not directly comparable to previous year's results.

The new KPI framework will measure "speed of grant development" as the average time taken between the kick-off meeting for Grant Agreement Development (GAD) and the submission of the package of GAD documents to the Executive Board.

Results 4.4 Median number of days from Board approval to grant signature

Project name	Signature date	Days from "go ahe-ad" to signature
CHAI ARV	24 Oct 2016	209
IBB ARV	29 Jun 2016	132
FIND HCV	04 Oct 2016	196
UOL ARV	01 Dec 2016	234
WITS ARV	01 Dec 2016	234
UNSW ARV	01 Dec 2016	234
WAMBO	07 Nov 2016	171
MEDIAN (AVERAGE)		209 (202)



KPI 5

Safeguarding Predictable and Stable Funding

Sustainable and predictable funding is essential for Unitaid to achieve its mission. France continues to be the largest contributor to Unitaid, making a contribution of US$100.6 million in 2016. The United Kingdom has committed GBP 44 million per year for 2015-2017 in the form of promissory notes. Other contributions were received in 2016 from Bill and Melinda Gates Foundation, Brazil, Cameroon, Chile, the Republic of Korea, and Norway. All contributions to Unitaid are voluntary, and recorded when a binding agreement is signed by Unitaid and the contributor.

KPI 5 "**Safeguarding predictable and stable funding**" summarizes the financial situation of the organization in respect of pledges received and change in number of donors.

5.1	**Per cent of pledges received for the next 3 years to the estimated amount needed to meet planned disbursements and mitigate risks**
5.2	**Per cent increase in number of Donors contributing to Unitaid annually**

5.1. Per cent of pledges received for the next 3 years to the estimated amount needed to meet planned disbursements and mitigate risks

The Unitaid Secretariat ensures that it has the required funds in place to meet contractual obligations. KPI 5.1 captures the essence of this objective. In practice, it should be noted that all funds or promissory notes for an investment must be deposited in the bank before a grant can be approved. As a result, 100 per cent of planned commitments are covered by contributions already received. Furthermore, Unitaid undertakes detailed forward-looking financial planning to identify resource needs, and matches this to ongoing resource mobilization efforts.

5.2.
Per cent of increase in number of donors contributing to Unitaid annually

Since its creation in 2006, Unitaid has received contributions from 18 different donors. In 2016, 7 donors made a direct contribution, an increase of two donors from 2015. When also accounting for the promissory notes from the United Kingdom (which can be deposited at a later date, subject to need) the number of donors increases from 7 to 8.

KPI 6

Aligning and Harmonizing with International Efforts to Improve the Health of People Living With HIV, TB and Malaria

Unitaid places strong emphasis on strengthening and leveraging partnerships with a focus on results. The importance of partnerships in support of Unitaid's role in global public health has two objectives:

1. Alignment on strategy and areas for intervention; and

2. Ensuring implementation of projects in the low resource countries, with a view to securing scale-up and sustainable impact, through complementarity (non-duplication) and efficient coordination of investments.

KPI 6 "**Aligning and harmonizing with international efforts to improve the health of people living with HIV, TB and malaria**" helps to measure the extent to which Unitaid is engaged in the global response to the three diseases.

In general, Unitaid aims to engage partners throughout the life-cycle of a grant (from inception to transition and scale-up) thus enabling partners to do more with less, ultimately providing the populations in need with quality, affordable and effective commodities for HIV, TB and malaria and making them available faster. KPI 6 is broken down into three sub-indicators to provide further insight into the extent to which Unitaid is working in partnership.

6.1	**Number of grants that include co-investment with other global public health donors and national programmes**
6.2	**Number of countries with Unitaid-supported medicines and diagnostics being part of their national programmes**
6.3	**Number of grants that have active participation by Civil Society in their grant agreements**

6.1. Number of grants that include co-investment with other global public health donors and national programmes

Co-investment is defined as additional support, financial or in-kind, provided to a grant to ensure its success. This measures the support that other global health donors provide to the work of Unitaid and demonstrates that they value the investments that Unitaid is making to shape the markets for products of public health importance. More than 50 per cent (18 of 35 projects) of all active grants (listed in Annex 1) were being co-financed by partners in 2016, an increase of one compared to last year (17 projects), and a higher number (and proportion) than the first two years of the strategic period.

Results 6.1 Number of grants that include co-investment with other global public health donors and national programmes

Disease Areas	Project	Grantees	Main co-Investors
Cross-cutting	WHO PQ Diagnostics II	WHO-EMP	BMGF
	WHO PQ Medicines II	WHO-EMP	BMGF
	WAMBO	The Global Fund	The Global Fund
HIV	MSF	MSF	MSF
	ARV first line (ADVANCE)	Wits RHI	USAID/ PEPFAR
	Enabling Access to new generation 1st line ARVs in LIC	Institut Bouisson Bertrand (IBB)	ANRS
	ARV D2EFT	University of New South Wales (UNSW)	The National Health and Medical Research Council, Australia.
	HIV Self-Testing Africa (STAR)	PSI	BMGF, DFID
	OPP-ERA Phase 2	Solthis	ANRS
	Paediatric ARV formulations	DNDi	French Development Agency, MSF, UBS Optimus Foundation
Hepatitis	Access to the HCV treatment revolution	MSF	MSF
Malaria	Private Sector Market for RDTs	PSI	DFID
	Quality Assurance of Rapid Diagnostic Test	FIND	BMGF, DFID
	ACT Watch-2	PSI	BMGF, DFID
	Market Intervention to Accelerate Uptake of New Vector Control Tools-Next Generation Indoor Residual Spraying	IVCC	PMI, The Global Fund
TB	STEP Paediatric TB	TB Alliance	USAID
	TB Xpert	WHO	BMGF
	Expand New Drugs for TB	Partners in Health	USAID (donation of bedaquiline)

6.2. Number of countries with Unitaid-supported medicines and diagnostics being part of their national programmes

KPI 6.2 measures how widely medicines and diagnostics, supported by Unitaid, are being used across countries. For 2016 KPI reporting, the methodology has been revised due a change in the availability of data, and which in some cases aggregates the number of countries with reported uptake of Unitaid supported medicines and diagnostics*.

The new results include both the project countries and countries from GF/PEPFAR databases. Table 6.2 below shows the number of countries with Unitaid-supported medicines and diagnostics as part of their national programmes. For the most part, the number of countries has risen compared to results we reported in Unitaid's KPI Report 2015. For example, injectable artesunate is now reported to being used in 27 countries, based on 2016 procurement data (with 30 countries having adopted injectable artesunate as the preferred approach to treating severe malaria). One new product has also been included in the table this year, as a result of Unitaid's investment into next generation Indoor Residual Spray (through the IVCC project) - Actellic.

Results 6.2 Number of countries with Unitaid-supported medicines and diagnostics being part of their national programmes

	Project	Product name	2016
Cross	TB Xpert (WHO)	Rapid TB testing using GeneXpert MTB/RIF testing platform	130
	HIV POC VL testing in low resource settings	POC VL	19
	HIV POC EID testing in low resource settings	POC EID	13
	HIV POC CD4 testing in low resource settings	POC CD4 tests	30
Medicines	Improving severe malaria outcomes	Injectable Artesunate	27
	CHAI Paediatric ARV Project	Nevirapine/Lamivudine/Zidovudine 50/30/60 mg	44
	CHAI 2nd- line ARV project	Atazanavir/Ritonavir 300/100 mg	38
	IVCC	Actellic	4

* In the case of the "HIV POC testing in low resource settings" projects, the numbers presented in the table above reflect several products across several projects.

6.3.
Number of grants that have active participation by Civil Society in their grant agreements

Civil Society is critical to raising community awareness about new and existing products that prevent, diagnose and treat the three diseases. Without strong Civil Society support and targeted advocacy within the communities living with the three diseases, Unitaid's investments would be limited in their scope and impact.

Some 27 (93 per cent) of the 29 projects in scope of this KPI include CSO engagement in the project plans. Unitaid continues to work with implementing partners during grant development to ensure active civil society engagement is a consistent part of each project implementation strategy, as appropriate.

In addition, a Civil Society Engagement Plan was signed between Unitaid and Civil Society representatives in March 2016. This plan aims to strengthen the relationship between Unitaid and Civil Society, through information sharing and feedback on Unitaid projects, the promotion of demand generation and transition of Unitaid-supported products, increased dialogue with Civil Society networks, strengthened consultation processes, leveraging Civil Society's expertise on intellectual property, supporting resource mobilization efforts, building Civil Society activities into proposals and the reporting of Civil Society engagement activities and outcomes to the Executive Board on a regular basis.

KPI 7

Resource Management

Unitaid strives to maximise the amount of its financial resources that can be invested to improve access to life-saving tests, treatments and preventive products for people living with HIV/AIDS (and related co-infections), TB and malaria. KPI 7 assesses Unitaid's "**Resource Management**", with three sub-indicators reflecting Unitaid's commitment to maintaining an efficient, effective and gender-balanced Secretariat capable of implementing and managing its portfolio effectively.

7.1	**Per cent Secretariat costs relative to total value of active grants (reported semi-annually)**
7.2	**Level of respondent satisfaction with working at Unitaid (from an anonymous, electronic survey of staff)**
7.3	**At least 40 per cent representation of each gender in Unitaid's senior professional staff**

7.1. Per cent Secretariat costs relative to total value of active grants

Unitaid continues to maintain a lean organizational structure relative to the value of the active portfolio it manages. The Secretariat is charged with implementing the organization's core business and grant management in ways that maximise efficiency and effectiveness. In 2016, Secretariat costs represent 2.01 per cent of the active grant portfolio value, which is consistent with 2015 performance.

7.2. Level of respondent satisfaction with working at Unitaid (from an anonymous, electronic survey of staff)

Unitaid continues to strive to build an empowering environment for all staff. A staff survey measures staff satisfaction. No staff survey was completed in 2016, and is due to be completed in mid-2017.

7.3. Ratio of women to men in Unitaid's professional staff (FTEs)

As at 31 December 2016, Unitaid had 67 staff in total, split into 42 (63 per cent) female staff, and 25 (37 per cent) male staff. The Secretariat contained 58 professional staff members, split into 34 female professional staff members (59 per cent) and 24 male professional staff members (41 per cent). The percentage of female staff at senior professional level (P4 and above) was 56 per cent and male was 44 per cent.

Looking forward

Key Performance Indicators for 2017-2021

Unitaid's Mission for 2017–2021 is to "Maximize the effectiveness of the global health response by catalyzing equitable access to better health products", which is underpinned by three strategic objectives – 1) Innovation - Unitaid connects innovators who develop better health products with people who need them the most, 2) Access - Unitaid overcomes barriers to access to health products, and 3) Scalability - Unitaid works with partners to realize the full impact of its interventions and to ensure scale-up.

Four investment commitments support the 2017-2021 Strategy – 1) We strive for equity, 2) We maximise Value for Money, 3) We succeed in partnership and 4) We invest in products that impact health systems.

Alongside the 2017-2021 Strategy, Unitaid has developed new Key Performance Indicators, which are split into two categories – (i) Strategic KPIs and (ii) Operational KPIs.

The Strategic KPIs are positioned to demonstrate impact. They can help key stakeholders - such as countries and scale-up partners - to make better investment decisions. In turn, these decisions can accelerate equitable access, at scale, of better health products and approaches. The Strategic KPIs are directly linked to our Value for Money framework, which defines Unitaid's impact as:

- Direct - the direct outcomes of Unitaid's investment (i.e. generated over the life of a project) and;
- Indirect - impact generated indirectly through funding partners and countries investing in health products and approaches originally supported by Unitaid at scale.

Indirect impact is projected at the end of a project, and will be verified through an external impact evaluation for a period of five years beyond the project. The "Mission" indicators of Unitaid include:

- KPI 1.1 – Increasing Public Health Impact. This measures, (i) the additional number of lives saved and (ii) the additional number of infections (HIV or TB) or cases averted (malaria) from access to better health products and approaches supported by Unitaid.

Furthermore, Unitaid investments generate savings and efficiencies for health systems, through the utilization at scale of better health products and approaches. This impact will be measured in:

- KPI 1.2 – Generating efficiencies and savings. Examples of potential savings include the introduction of products that are more affordable (due to price reductions), or more cost-effective, e.g. that result in the avoidance of other costs (e.g. hospitalization, progression to expensive second line treatments, logistics costs), or that require less time from qualified healthcare professionals.

Finally, Unitaid aims to measure its Return on Investment through:

- KPI 1.3 – Delivering positive returns. This metric is the ratio of benefits (e.g. the public health impact and/or savings/efficiencies of Unitaid-supported products or approaches, translated into monetary terms) to costs (both direct Unitaid investment cost, and costs of long-term delivery by partners or governments).

Unitaid also has two KPIs about equity - KPI 2.1, Investing for the poorest, and KPI 2.2, Investing for the underserved, which ensure that 100 per cent of Unitaid's investments are designed to benefit the poorest countries and underserved groups in respect of the specific disease context.

Direct impact will be measured within project log frames and two Strategic KPIs:

- KPI 3 – Catalyzing Innovation. This measures the number of product development activities successfully completed as a result of Unitaid support over 2017-2021.

- KPI 4 – Overcoming market barriers. This measures progress against the Access objective, the total number of critical access barriers overcome during the strategic period, covering areas such as Quality, Affordability, Demand & Adoption and Supply & Delivery.

The link between the end of a project and long-term impact is the extent to which the outcomes of a Unitaid investment are transitioned and scaled-up by other funding partners and countries. This will be measured through two KPIs:

- KPI 5.1 - Securing funding. This measures, at the point of grant closure, the proportion of relevant countries (project countries and non-project countries) where sufficient funding has been secured through a key funding partner or a country to offer scale-up of a health product or approach supported by Unitaid.

- KPI 5.2 - Scaling-up coverage. This measures, over a period of up to two years beyond grant closure, the additional number of people who will benefit from a better health product or approach supported by Unitaid.

The Operational KPIs cover a range of areas including (i) Finance – Secretariat financial efficiency and resource mobilization, (ii) Grant Agreement Development – speed of grant development, (iii) Grant implementation – covering timeliness of reporting, disbursement, and grantee responsiveness to implement action points, as well as the status of financial audit and risk management. Finally, there are also KPIs relating to (iv) Human Resources – including measuring timeliness of staff performance management and development reviews, and overall staff satisfaction within the Unitaid Secretariat.

Performance against the Strategic and Operational KPIs will be reported for the first time in June 2018.

Annex 1

Portfolio overview (covering active, new, and closing projects)

Cross Cutting	
Grant	**Lead grantee(s)**
Access to treatment for PLHIV in MIC	ITPC
Medicines Patent Pool Foundation II	MPP Foundation
Preventing Patent Barriers	Lawyers Collective
WAMBO	The Global Fund
WHO PQ Diagnostics II	WHO-EMP
WHO PQ Medicines II	WHO-EMP
HIV	
Grant	**Lead grantee(s)**
Access to the HCV treatment revolution	MSF
ADVANCE Clinical Trial	Wits (University)
ARV DolPHIN 2 trial	UoL (University of Liverpool)
ARV NAMSAL Clinical trial	Institut Bouisson Bertrand
CHAI Optimal ARVs	CHAI
Access to CHAI/UNICEF-Point of Care Diagnostics phase 2b	UNICEF, CHAI
D2EFT Clinical Trial	UNSW (University of New South Wales)
EID & VL Monitoring	Diagnostics for the Real World
Global Network on HIV Monitoring Technologies	LSHTM
HIV CD4 and VL Diagnostics	MSF
HIV Self-Testing Africa (STAR)	PSI
HIV/HCV Drug Affordability Project	Coalition Plus
Introduction of Point Of Care EID in decentralized settings	Elizabeth Glaser Pediatric AIDS Foundation
IPMA	CHAI
OPP-ERA Phase 1	FEI
Paediatric ARV formulations	DNDi
Unlocking the Hepatitis C diagnostic and treatment	FIND
OPP-ERA Phase 2	Solthis
WHO HTM Enabler sub-grant HIV/HCV	WHO
PrEP	UNICEF

Malaria	
Grant	**Lead grantee(s)**
Accelerating Uptake of New Vector Control Tools	IVCC
Access to SMC Services	Malaria Consortium
ACT Watch-2	PSI
Improving Severe Malaria Outcomes - Inj AS	MMV
Private Sector Market for RDTs	PSI
Quality Assurance of Rapid Diagnostic Test	FIND
TB	
Grant	**Lead grantee(s)**
Expand New Drugs for TB	Partners in Health
STEP Paediatric TB	TB Alliance
TB Xpert	WHO-GTB

Lead Grantees in 2016

Grantee	Project
PSI	ACT Watch - 2
LSHTM	Global Network on HIV Monitoring Technologies
Medicine Patent Pool Foundation (MPP Foundation)	Medicine Patent Pool II
WHO	PQ Diagnostics
WHO	PQ Medicines
The Global Fund	Wambo
CHAI / UNICEF	Access to Point of Care HIV Diagnostics - phase 2a
CHAI / UNICEF	Access to Point of Care HIV Diagnostics - phase 2b
MSF	Access to the HCV diagnosis and treatment
Tides Center (ITPC)	ITPC
University of Liverpool (UOL)	ARV Dolphin 2
Wits RHI	ARV first line (ADVANCE)
CHAI	CHAI ARV
Institut Bouisson Bertrand (IBB)	Enabling Access to new generation 1st line ARVs in LIC
PSI	HIV self-testing (STAR) phase 1
Coalition Plus International	HIV/HCV Drug Affordability Project - Ph1
MSF	CD4 and VL testing
CHAI	IPMA

Grantee	Project
EGPAF	Introduction of Point of Care EID
Solthis	OPP-ERA Phase 2
DNDi	Paediatric ARV formulations
DRW	SAMBA
FIND	HCV
Malaria Consortium (MC)	Access SMC
PSI	Private Sector Market for RDTs
Lawyers Collective	Preventing patent barriers
FIND	Quality Assurance of Rapid Diagnostic Test
Partners in Health (PIH)	Expand New Drugs for TB
TB Alliance	STEP TB - Paediatric TB Centre for Excellence
Medicines for Malaria Venture (MMV)	ISMO
Stop TB Partnership	TB Xpert
IVCC	Market intervention to accelerate uptake of new

Annex 2

1.1 IVDS Prequalified and Newly Prequalified for Unitaid Priority Diseases

Product name	Country	Dossier assessment procedure	Date of prequalification
HIV			
Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	China	Full Assessment	15 Feb 16
AiD anti-HIV 1+2 ELISA	China	Full Assessment	15 Feb 16
Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost®/TMB	Germany	Abridged Assessment	22 Mar 16
MP Diagnostics HIV Blot 2.2	Singapore	Abridged Assessment	06 Apr 16
OraQuick HIV 1/2 Rapid Antibody Test	USA/Thailand	Full Assessment	08 Apr 16
DPP® HIV 1/2 Assay	USA	Full Assessment	06 Jun 16
Alere q HIV-1/2 Detect	Germany	Full Assessment	13 Jun 16
Xpert® HIV-1 Qual Assay Xpert® with GeneXpert Dx, GeneXpert Infinity-48s, and GeneXpert Infinity-80	Sweden	Abridged Assessment	13 Jun 16
Alere™ HIV Combo	Japan	Full Assessment	11 Jul 16
First Response® HIV 1-2-0 Card test	India	Full Assessment	14 Jul 16
Diagnostic Kit for HIV(1+2) Antibody (Colloidal Gold) V2	China	Full Assessment	21 Dec 16
HCV			
SD BIOLINE HCV	South Korea	Full Assessment	29 Nov 16

1.2 FPPS Prequalified and Newly Prequalified for Unitaid Priority Diseases

Product name	Dosage form & strength	Country	Dossier assessment procedure	Date of prequalification
HIV				
Lamivudine/Zidovudine	Tablet - Film-coated, 150mg/300mg	India	SRA Approved Generic	10 Feb 16
Sulfamethoxazole/ Trimethoprim	Tablet, 400mg/80mg	India	Full Assessment	23 May 16
Sulfamethoxazole/ Trimethoprim	Tablet, 800mg/160mg	India	Full Assessment	23 May 16
Emtricitabine/Tenofovir disoproxil (fumarate)	Tablet - Film-coated, 200mg/300mg	India	Full Assessment	27 May 16
Ceftriaxone (sodium)	Powder for solution for injection, 1g	China	Full Assessment	15 Aug 16
Lamivudine	Tablet - Film-coated, 150mg	India	Full Assessment	26 Oct 16
Tenofovir disoproxil (fumarate)	Tablet - Film-coated, 300mg	South Africa	Full Assessment	07 Dec 16
Emtricitabine/ Tenofovir disoproxil (fumarate)	Tablet - Film-coated, 200mg/300mg	South Africa	Full Assessment	07 Dec 16
Efavirenz	Tablet - Film-coated, 600mg	South Africa	Full Assessment	07 Dec 16
Darunavir	Tablet - Film-coated, 400mg	India	Full Assessment	21 Dec 16
Darunavir	Tablet - Film-coated, 600mg	India	Full Assessment	21 Dec 16
Isoniazid/ Pyridoxine (hydrochloride)/ Sulfamethoxazole/ Trimethoprim	Tablet, 300mg/ 25g/800mg/160mg 300mg/25mg/ 800g/160mg	India	Full Assessment	21 Dec 16
Abacavir (sulfate)/ Lamivudine	Tablet - Dispersible, 120mg/60mg	India	Full Assessment	21 Dec 16
Lamivudine/ Tenofovir disoproxil (fumarate)	Tablet - Film-coated, 300mg/300mg	India	Full Assessment	21 Dec 16
HCV				
Daclatasvir (dihydrochloride)	Tablet - Film-coated, 30mg	United States of America	SRA Approved Innovator	14 Oct 16
Daclatasvir (dihydrochloride)	Tablet - Film-coated, 60mg	United States of America	SRA Approved Innovator	14 Oct 16

Product name	Dosage form & strength	Country	Dossier assessment procedure	Date of prequalification
TB				
Capreomycin (sulfate)	Powder for solution for injection, 1000mg	India	Full Assessment	10 May 16
Moxifloxacin (hydrochloride)	Tablet, coated 400mg	India	Full Assessment	11 Jul 16
Linezolid	Tablet - Film-coated, 600mg	India	Full Assessment	11 Jul 16
Ethionamide	Tablet - Film-coated, 125mg	India	Full Assessment	11 Jul 16
Levofloxacin	Tablet - Film-coated, 250mg	India	Full Assessment	07 Sep 16
Levofloxacin	Tablet - Film-coated, 500mg	India	Full Assessment	07 Sep 16
Rifampicin	Capsules - Hard, 150mg	India	Full Assessment	07 Sep 16
Isoniazid/ Rifampicin	Tablet - Film-coated, 150mg/300mg	India	Full Assessment	15 Sep 16
Moxifloxacin (hydrochloride)	Tablet - Film-coated, 400mg	India	Full Assessment	26 Oct 16
Ethambutol (hydrochloride)/ Isoniazid/ Pyrazinamide/ Rifampicin	Tablet - Film-co-ted, 275mg/75mg/ 400g/150mg	India	Full Assessment	07 Dec 16
Pyrazinamide	Tablet, Dispersible 150mg	India	Full Assessment	07 Dec 16
Linezolid	Tablet - Film-coated, 600mg	India	Full Assessment	07 Dec 16

1.3 Apis Prequalified and Newly Prequalified for Unitaid Priority Diseases

INN	Country	Dossier assessment procedure	Date of prequalification
HIV			
Emtricitabine	India	Non-standard*	29 Jan 16
Lopinavir	India	Full Assessment	17 Aug 16
Malaria			
Lumefantrine	India	Full Assessment	17 Aug 16
Dihydroartemisinin	India	Full Assessment	31 Oct 16
TB			
Kanamycin (acid sulfate) - sterile	China	Full assessment	03 Feb 16
Ethambutol (hydrochloride)	India	Full assessment	25 May 16
Cycloserine	Republic of Korea	Non-standard*	09 Jun 16
Streptomycin (sulfate) - sterile	China	Full assessment	14 Jun 16
Rifampicin	China	Non-standard*	15 Jul 16
Levofloxacin	China	Non-standard*	12 Sep 16
Cycloserine	China	Full Assessment	07 Dec 16

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