Improving Access for Quality-Assured TB Medicines and Diagnostics

Access to Quality and Affordable Drugs through the Global Drug Facility

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Stop TB Partnership
GLOBAL DRUG FACILITY

What is the Global Drug Facility (GDF)?

An initiative of the Stop TB Partnership (2001), mainly funded by USAID, hosted in UNOPS and managed by the Stop TB Partnership secretariat

An operating mechanism to support the Stop TB Strategy Goal 3:

- to facilitate world-wide, equitable access to TB medicines and diagnostics, including new tools, across public and private sectors.

GDF began supplying FLDs in 2001, and in 2007 added the supply of SLDs & pediatric medicines & 2010 new diagnostics (key source for GeneXpert); BDQ – 2014, DLM - 2016

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GDF Strategic Objectives

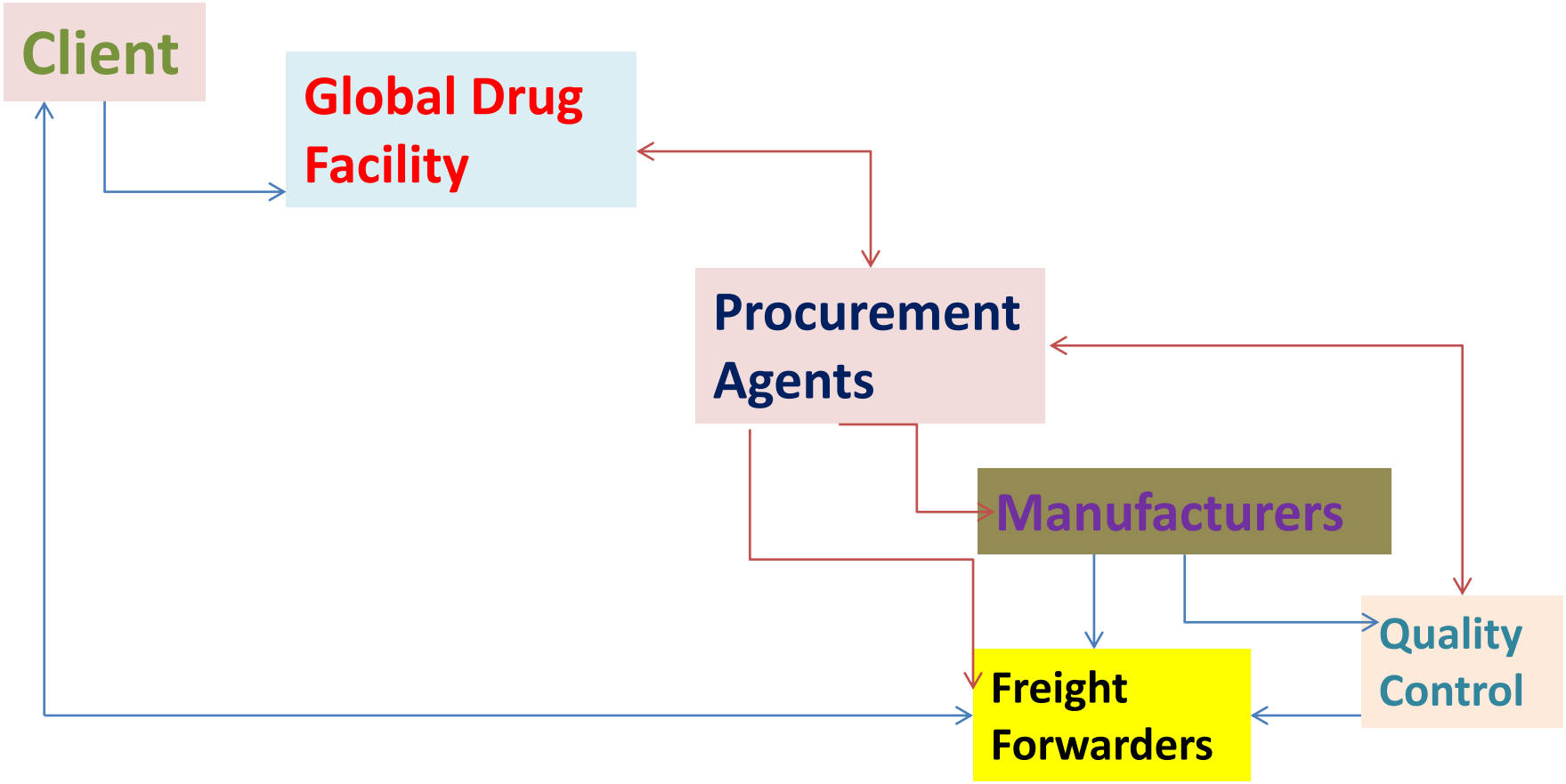
1. Manage and coordinate market activities across all stakeholders for the full portfolio of TB medicines, regimens, and diagnostics

2. Develop state-of-the-art business intelligence and data-driven approaches through early adoption of cutting-edge technology

3. Undertake strategic procurement and execute innovative logistics solutions for TB medicines and diagnostics

4. Accelerate the uptake of new TB medicines, regimens, and diagnostics using GDF "launchpad" in close collaboration with TB Reach and WHO's working groups on new TB medicines

GDF model


Client
Global Drug Facility
Procurement Agents
Manufacturers
Quality Control
Freight Forwarders

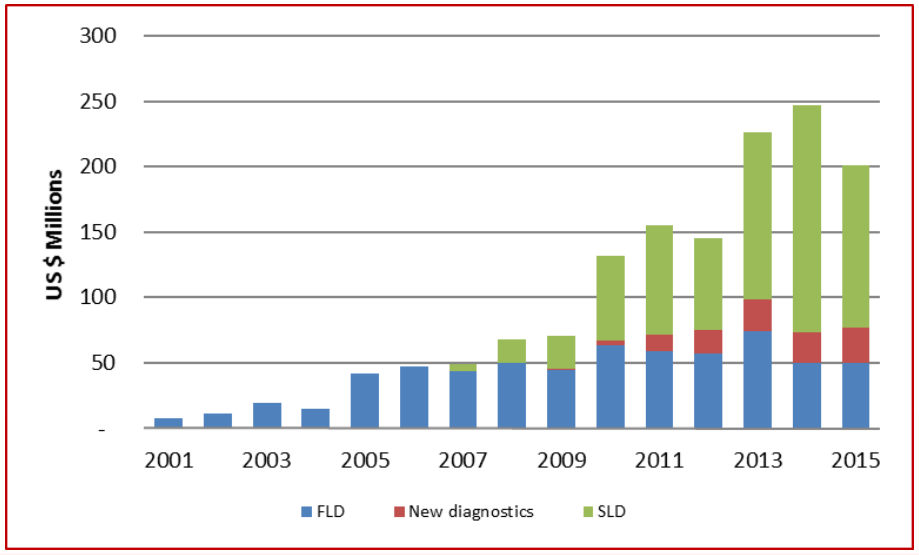
Key GDF Milestones

133 countries benefited from GDF procurement / bundled mechanism with

- > 25.5 M Adult FLD treatments
- > 1,5 M pediatric treatments
- > 197,778 SLD patient treatments

=> 27M treatments delivered as of 2015 since GDF inception in 2001

GDF has processed orders for TB products with a total value of approximately US $1.44 billion since 2001



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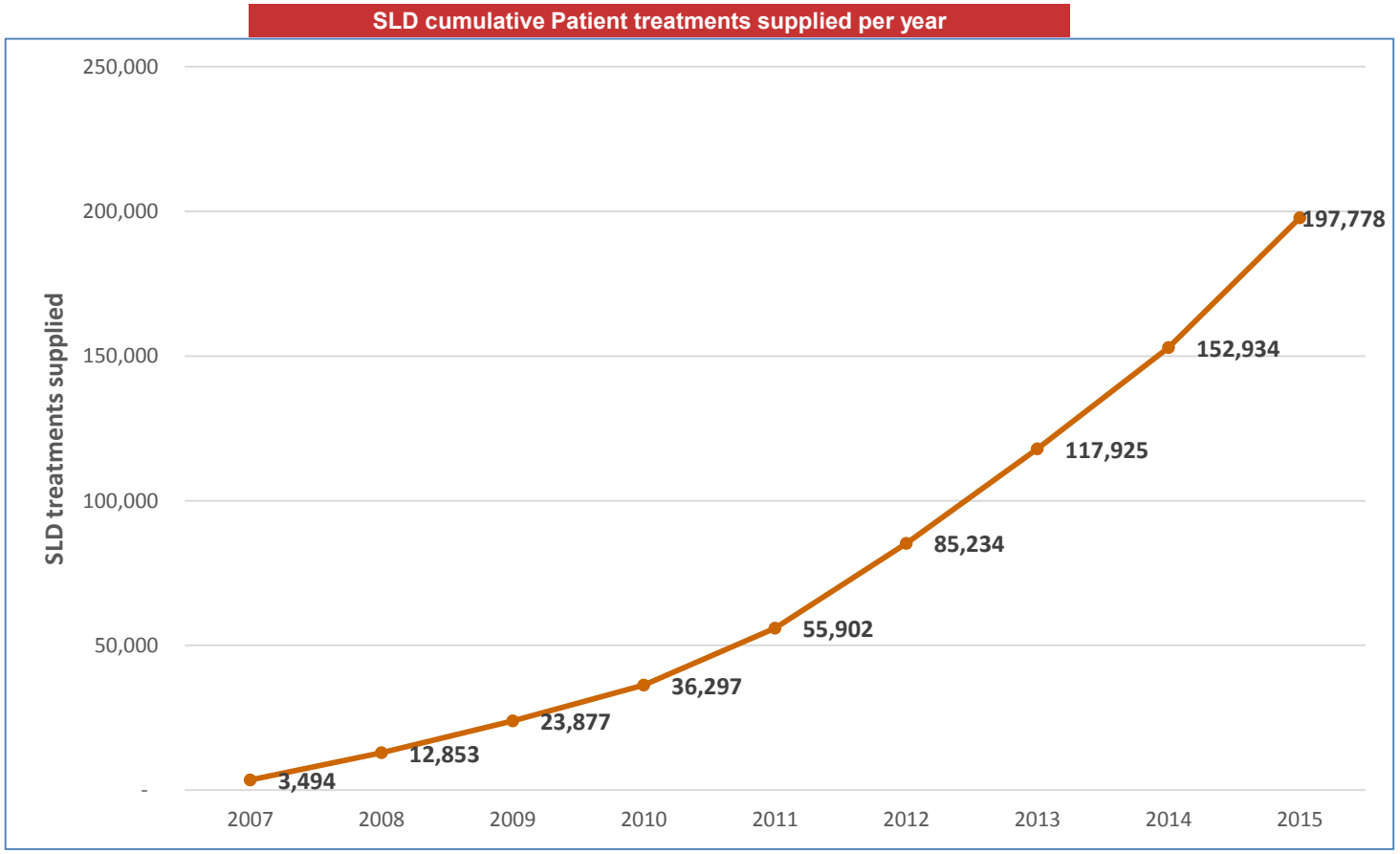
MDR Treatments supplied



Capacity building and technical assistance

In only 2015, 46 **monitoring/technical assistance missions** were conducted to support countries with:

- tailored technical assistance,
- provision of innovative tools to countries/organizations in need and
- enhancing partners' engagement for technical and financial support.
- strengthen national capacity for procurement and supply chain management.

Expanding capacity building outreach:

- strong collaboration with key partners, e.g. the Global Fund, UNION, MSH and KNCV.
- GDF is actively engaged with various partners, such as DR-TB Scale-up Treatment Action Team (STAT), NTPs, MSF, PIH and the Global Fund to improve demand and supply coordination

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GDF Product Portfolio

1st and 2nd Line Anti-TB Drugs

RATIONAL USE

Providing an uninterrupted supply

Bedaquiline
Delamanid

Paediatric Anti-TB Drugs

AN INCLUSIVE APPROACH

Supplying appropriate anti-TB drugs for children, who also have the right to be treated.

New paediatric formulation available

Competitive Pricing

SIGNIFICANT SAVINGS

Pooling procurement enables GDF to offer the most competitive prices, equitably.

Diagnostic Kits

CASE-FINDING

Offering practical diagnostic tools for laboratories to improve case-finding.

New Diagnostics

Tackling the problem in innovative way

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Goal of GDF QA Policy

- To guarantee the Safety, Efficacy and Quality of the Finished Pharmaceutical Products (FPP) procured through GDF

- The products to be:
  - ✓Recommended for use by WHO
  - ✓Authorized for use by NDRA of recipient countries
  - ✓Product Quality Monitoring Programme in place

Model quality assurance system for Procurement Agencies:
http://apps.who.int/medicinedocs/documents/s21492en/s21492en.pdf

Stringent standards

Anti-TB medicines	Diagnostics
WHO-PQ [1], **or** **Approved by a Stringent Regulatory Authority (SRA)** = ICH members, observers and associates [2]	**Authorized for use in destination country**
If products meeting these criteria are not available on the market:	**WHO recommended**
ERP authorized products	**Mostly SRA** approval

1. WHO Prequalification of Medicines Programme **(PQP):** www.who.int/prequal
2. **SRAs:** Listed in each organization's QA policy

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Rapid risk assessment by Expert Review Panel (ERP)[1]

Dossier assessment

Product dossier must have been accepted for review by WHO-PQP or a SRA (if the medicine/strength is invited for WHO prequalification)

▶**ERP** reviews abridged dossier

Inspection

Manufacturing site (production line) must be GMP-certified
by WHO-PQP or
by an ICH or PIC/s member

▶ **ERP** verifies GMP status

Positive ERP opinion is valid for one year

Outcomes[2] are used by:

GDF; Global Fund; UNITAID, UNFPA; MSF; ICRC; UNICEF (for ACTs)

1. Expert Review Panel, hosted by WHO. More information on ERP: http://apps.who.int/prequal/info_press/pq_news_27April2012_ERP.htm
2. ERP-approved products are listed online at www.theglobalfund.org/en/procurement/quality/pharmaceutical/#Lists

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Bidding

- **Frequency of Bidding:**
  1. FLDs: every 1-2 years
  2. For SLDs: each year (in 2016 India and ROW combined)
  3. April to April

On behalf of the Stop TB Partnership Global Drug Facility (GDF), the GDF contracted procurement agent invites eligible suppliers (compliant with GDF's Quality Assurance policy and procedures) to submit a bid for the items described in the Invitation to Bid (ITB).

- **Bidding's Objective: adherence with principles of public procurement**
  1. Best value for money
  2. Fairness, integrity and transparency
  3. Effective international competition
  4. Interest of the organisation

Bidding

- **Evaluation of the bids and awards based on:**
  1. Price (lowest)
  2. Supplier performance on delivery lead time (highest)
  3. Shelf life (longest)
  4. Production lead time (shortest)
  5. Minimum Oder Quantity (lowest)
  6. Product registration (most)

- **Market share allocation***

  100%/0% for primary-sole supplier/auxiliary supplier
  55%/45%/0% for primary/secondary/auxiliary supplier(s)
  50%/30%/20%/0% for primary/secondary/tertiary/auxiliary supplier(s)

*allocation is indicative only, and the actual allocation might deviate due to importation requirements, client preferences, registration status and other factors as deemed necessary by GDF or its clients.

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GDF Product Catalogue

Stop TB Partnership | Glob

stoptb.org/gdf/drugsupply/drugs_available.asp

Apps Gmail OMS Converter | OANDA Travel | OANDA checkmytrip World Clock WHO Directory GMaps Other bookmarks

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FIND. TREAT. CURE TB.

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Home › Global Initiatives › Global Drug Facility › Procurement and Supply

GDF Product Catalogue

GDF aims to ensure the timely delivery of first- and second-line tuberculosis drugs and diagnostics at sustainable prices.

The Product Catalogue displays the highest and lowest product prices offered by GDF's principal suppliers. For the majority of products, GDF maintains long-term agreements with multiple suppliers, with target market share allocations depending on supplier status (primary/secondary/tertiary/quaternary). Allocations and supplier status may vary depending on performance, product status and other criteria monitored by GDF and its Procurement Agent. Volume discounts are available for most products. GDF and its Procurement Agent also hold contracts with back-up suppliers and occasionally, products from these suppliers are offered by GDF. Prices of these products may deviate from the range shown in the Catalogue. For budget purposes, GDF clients are strongly advised to utilise the highest product prices displayed in the Catalogue.

Click here to browse our 2014 Product Catalogue in PDF

You can also browse products online and click here for information on Bedaquiline.

Prices are valid until*:

- First Line Medicines, Medical Devices: 31 December 2014
- Second Line Medicines: 31 March 2015

* Prices may be subject to change in exceptional cases

For enquiries please email gdf@who.int

The benefits of GDF quality-assured products

GDF products enable physicians to treat patients according to the latest WHO treatment guidelines. All GDF products are on the WHO Essential Medicines List, which facilitates registration and importation. The use of Fixed Dose Combination (FDC) tablets greatly contributes to rational drug use and assists in effective implementation and expansion of the STOP TB Strategy. FDC tablets reduce the number of tablets a patient needs to take, while avoiding mono-therapy and thereby reduce the risks of developing Multidrug-

In This Section

- GDF Agents
- GDF Suppliers
- GDF Quality Assurance Policy
- Product Catalogue
- Track an Order
- Procurement Forms
- Procurement Notices
- Resource Materials

Quick Links

- Track an Order
- Product Catalogue
- Documents and Reports
- PSM Tools
- Send Feedback or Complaint

ISO 9001

GDF is ISO 9001:2000 compliant for provision of quality-assured anti-TB drugs and related services to eligible national TB control programmes.

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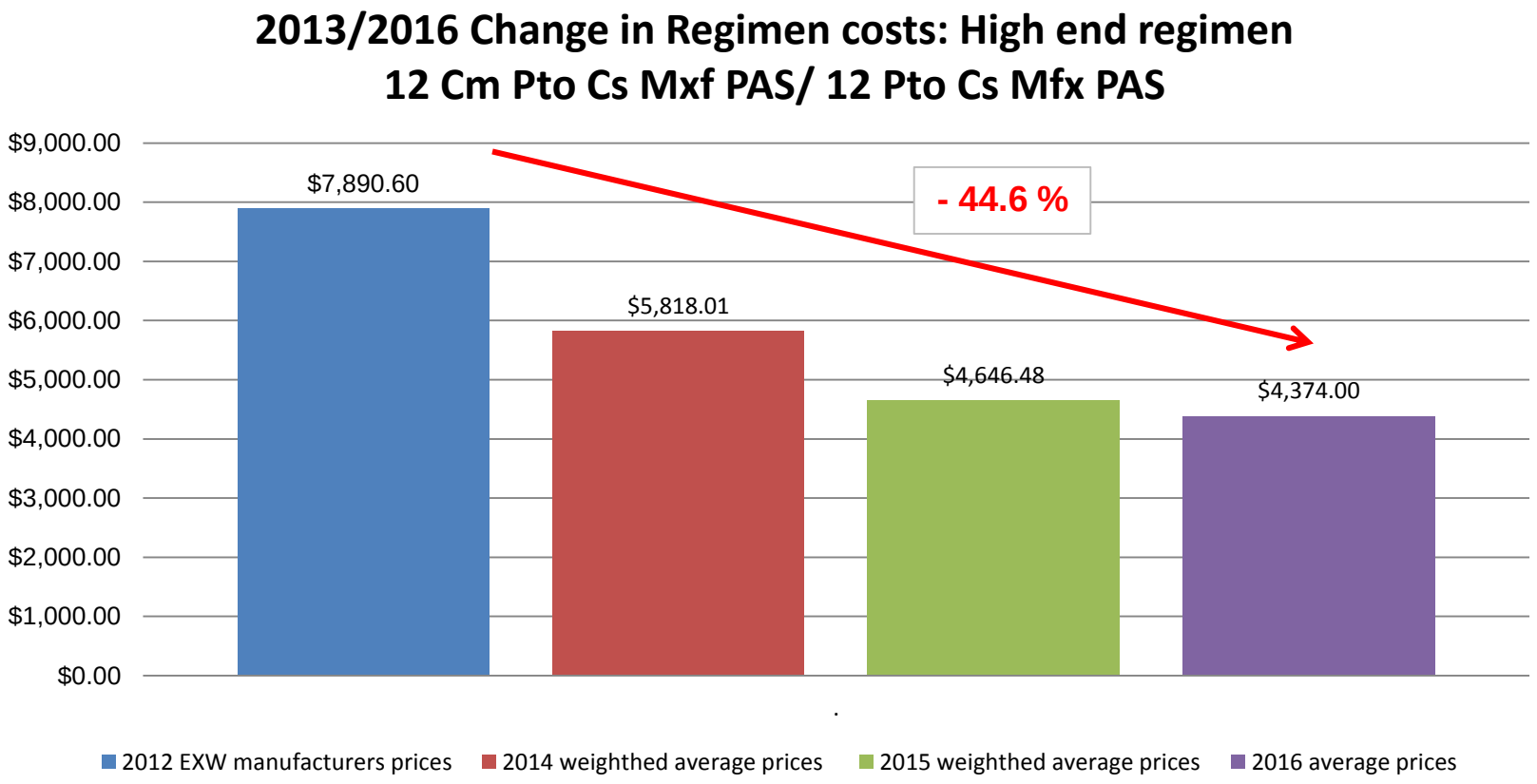
Key achievements

MDR Treatment Costs



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Key achievements

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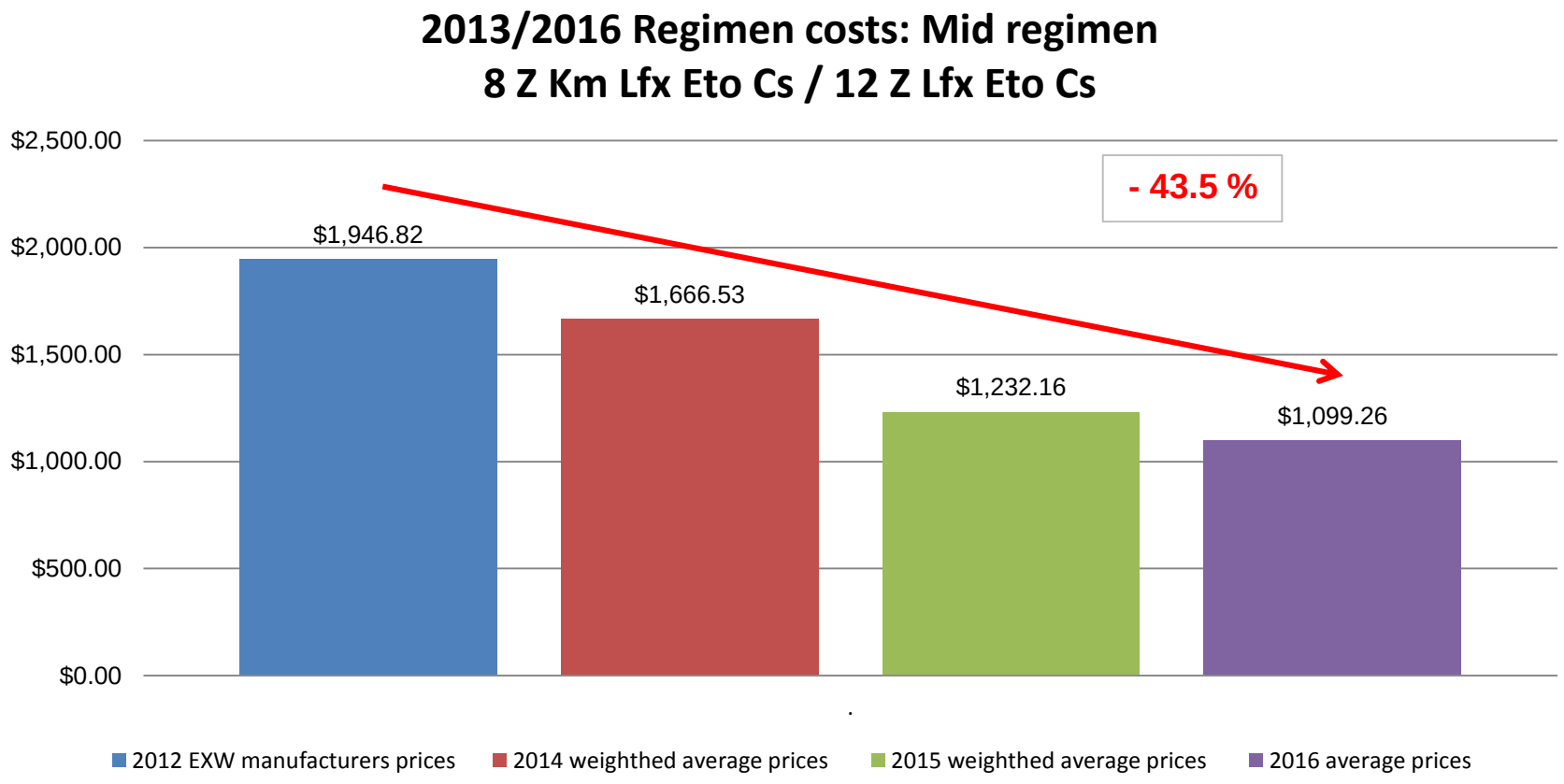
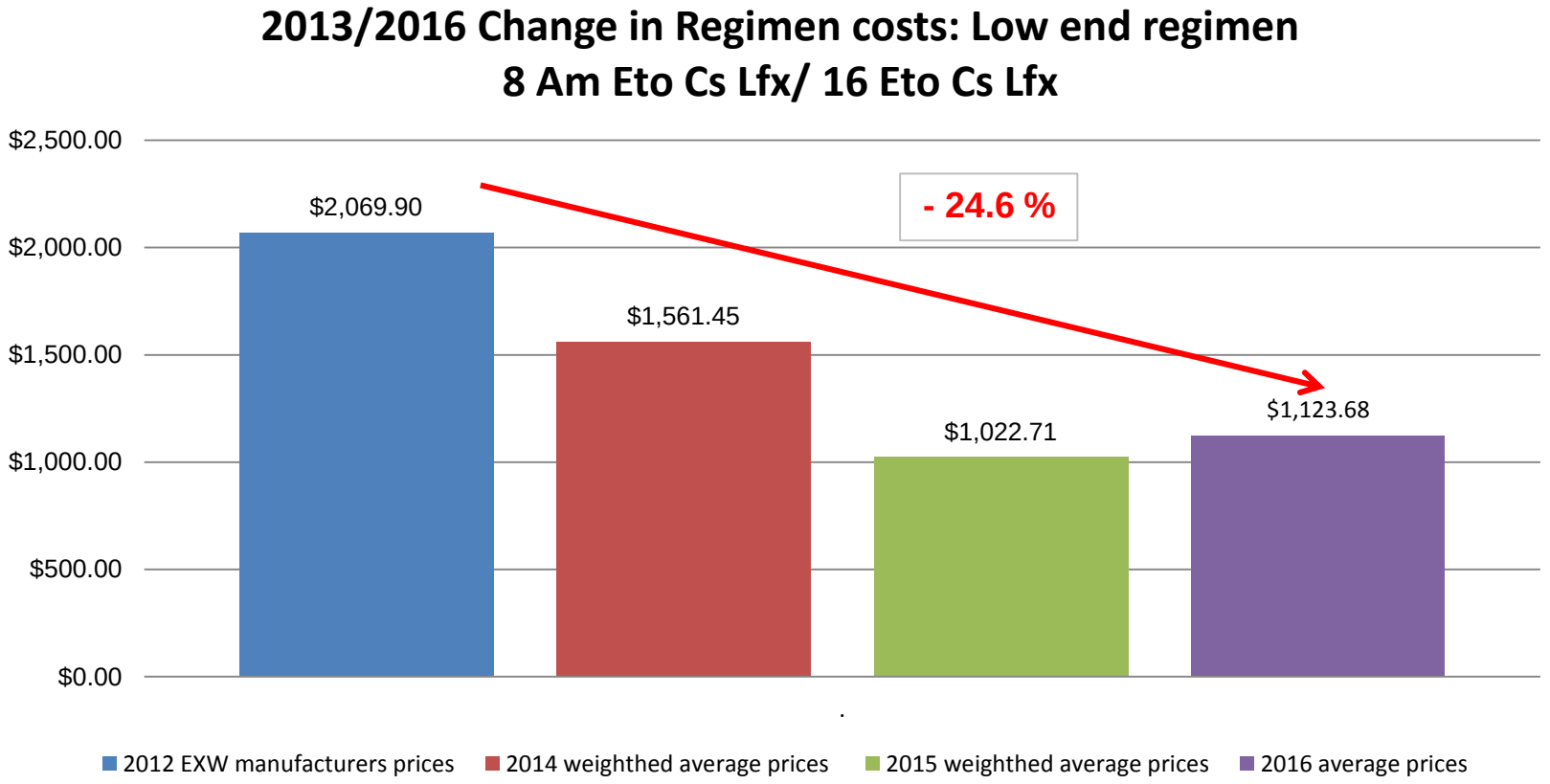


Key achievements

MDR Treatment Costs



Influenced by Cs price change vs 2015 (0.25 vs 0.20 USD per capsule)

The USAID Bedaquiline Donation Program

- March 6, 2015 USAID & Johnson & Johnson, signed an agreement to provide bedaquiline free-of-charge to eligible countries, according to WHO interim recommendations on the use of the drug.
- Under the agreement, Janssen will donate 30,000 treatment courses over a 4 year period.
- All countries eligible for Global Fund financing (>100) are eligible for the donation
- The donation is provided through USAID's agreement with the Stop TB Partnership's Global Drug Facility (GDF).
- Countries must declare that they are able to meet all five of the conditions as per the WHO Interim Policy Guidance on bedaquiline
  - If these 5 conditions are not met, countries can request Technical Assistance to USAID
  - Adverse events reported directly to Janssen or via GDF: BDQAE@StopTB.org

Delamanid Purchase via the GDF

- Effective 1 March, 2016 delamanid available for purchase via GDF
- Price USD 1,700 for a full treatment course (6 months)
- Over 100 countries eligible for TB Financing by the Global Fund to Fight AIDS, TB and Malaria can access delamanid via the GDF at this price
- Countries must declare that they are able to meet all five of the conditions as per the WHO Interim Policy Guidance on delamanid
  - Adverse events reported to Otsuka via the GDF: DLMAE@StopTB.org
- Delamanid will be added to GDF Strategic Rotating Stockpile

Summary Bedaquiline & Delamanid

- 2 New life-saving TB medicines for MDR-TB
- Both available via the GDF to countries eligible for Global Fund TB Financing
  - Bedaquiline via donation program
  - Delamanid at $1700/treatment course (6 months)
- Both Available in GDF Strategic Rotating Stockpile
- Both require submission of a form signed by NTP stating WHO Guidelines being followed – including pharmacovigilance
  - Bedaquiline adverse events filed directly to Janssen or via GDF;
  - Delamanid adverse events filed to Otsuka via the GDF

5 WHO Requirements for Use of Bedaquiline & Delamanid

1. **Effective treatment and monitoring:** Treatment must be closely monitored for effectiveness and safety
2. **Proper patient inclusion:** Special caution is required when bedaquiline is used in people aged 65 and over, and in adults living with HIV. Use in pregnant women and children is not advised.
3. **Informed consent:** Patients must be fully aware of the potential benefits and harms of the new drug, and give documented informed consent before embarking on treatment.
4. **Adherence to WHO recommendations:** four effective second-line drugs. Bedaquiline alone should not be introduced into a regimen in which the companion drugs are failing to show effectiveness.
5. **Active pharmacovigilance and management of adverse events:** ensure early detection and proper management of adverse drug reactions and potential interactions with other drugs.

Availability of new paediatric formulations

New paediatric formulations (RHZ & RH) are available from GDF

- ✓ Rifampicin 75mg + isoniazid 50 mg + pyrazinamide 150 mg
- ✓ Rifampicin 75 mg + isoniazid 50 mg

- Manufacturer: Macleods, ERP ½
- The products dissolve in water, have fruit flavour and are simple to administer.
- Technical assistance for development of a strategic plan for transition to the new paediatric formulations is available.
- Technical Briefing Note to switch to new paediatrics formulations:

http://stoptb.org/news/stories/2016/ns16_009.asp