Accessing Improved TB Medicines for Children

Update from the STEP-TB Project

TB Alliance | 20 YEARS OF IMPACT

Access to Child-Friendly TB Medicines

Each day, more than 500 children die of tuberculosis (TB), the world's deadliest infectious disease. Of the more than one million children who are estimated to develop active TB each year, approximately 52 percent are either undiagnosed or incorrectly diagnosed by doctors.[1] Those who were diagnosed had to rely on six months of bitter-tasting, improperly formulated medicines to fight the disease—until STEP-TB.

Starting in 2013, the Speeding Treatments to End Pediatric Tuberculosis (STEP-TB) project, led by TB Alliance in partnership with the World Health Organization (WHO), marshalled partners around the world to respond to this dire situation, engaging the pharmaceutical industry to develop better medicines for children with TB. The new medicines were introduced in 2016 and began to reach children around the world, setting a precedent for future action in the fight against TB. Today, more than one million treatment courses of the child-friendly formulations have been procured by more than 90 countries, which have about 95 percent of the estimated global childhood TB burden.[2]

BY THE NUMBERS

Market research and modelling conducted by STEP-TB made the case for private sector investment

1.1 million
new cases of active TB in children annually[1]

205,000
deaths from childhood TB each year[1]

67 million
latent infected cases in children[3]

The Situation

TB is a leading cause of illness and death among children, especially in low- and middle-income countries. Despite this, children with TB have long remained a low priority for stakeholders in both the TB and global health areas. Evidence of this neglect was seen after no new drugs were developed in response to a global policy change by the WHO, which called for anti-TB medicines in higher doses to effectively treat children with TB.

STEP-TB

In 2013, Unitaid responded to this urgent need with a major investment to establish the STEP-TB project, led by TB Alliance. STEP-TB sought to make significant progress in the health of the market for childhood TB medicines.

One of the critical steps achieved by the project was the engagement of pharmaceutical companies to develop the required medicines and co-invest in ensuring global availability, leading to regulatory filings across TB endemic countries, as well as WHO prequalification.

STEP-TB facilitated early availability and uptake of child-friendly formulations, which were made available through the Stop TB Partnership's Global Drug Facility (GDF). The new medicines were designed to be dissolvable in water, palatable to children, and in child-appropriate doses. At an average price of $15.54 (USD) for a full, six-month course of treatment, affordability was key to ensuring widespread access.

To support these efforts, market research and modelling work conducted by STEP-TB improved the understanding of the global burden. These findings, which resulted in nearly doubling the childhood TB burden estimates, reduced the potential business risk for pharmaceutical companies. Improved market intelligence, along with in-country research on procurement processes and regulatory pathways, also helped technical partners like Management Sciences for Health (MSH) work with countries to plan effectively for introduction.

Collaboration with a wide range of partners was essential. STEP-TB worked closely with national TB programs, as well as Unitaid, the primary donor for the project, MSH, UNICEF, The Global Fund, USAID, GDF, KNCV, Baylor and Stellenbosch universities, among others, leading to the effective implementation of policy changes, product transition planning, registration strategies and rapid uptake.

The Impact

STEP-TB made significant headway in revitalizing the pediatric market. New products were developed and made widely available at an affordable price beginning in 2016, and children around the world began to receive better TB medicines in the right doses. By the end of 2019, 94 countries, which have about 95 percent of the estimated global childhood TB burden, have procured these improved medicines.[2]

The project achieved broad impact across the field of childhood TB by raising the disease's visibility on the broader child survival agenda and leveraging partner networks, such as UNICEF, to draw global attention to this long-neglected crisis. This was supported by a range of communications efforts, including a project web portal, earned media coverage, and strong support from activists, key opinion leaders and celebrities.

STEP-TB has reshaped the market for pediatric TB drugs by reducing the barriers to entry, engaging in innovative collaborations to launch optimized products and mobilizing strong demand.

The Way Forward

With more than one million treatment courses ordered by more than 90 countries, the STEP-TB project has proven that the development and uptake of improved health products is achievable. Stakeholders must continue the work necessary to fully implement worldwide rollout and secure long-term sustainability of the market.

The STEP-TB project can serve as a model for future introduction of innovative, life-saving medicines.

STEP-TB TAKEAWAYS

- Improved estimates coupled with comprehensive market intelligence and demand-building significantly reduced business risks for pharmaceutical companies; gaps remain between the estimated disease burden and the number of children put on treatment.
- Active collaboration with pharmaceutical and global health partners has been key to success; in a small market, ensuring widespread adoption to create adequate scale and avoiding fragmentation contributed to ensuring affordable pricing and sustainable supply of products.
- Country preparation and the link to financial plans and buy-in from donors was crucial. Broad stakeholder involvement at the national level drove guideline and adoption decisions.
- True global availability and adoption required a two-fold approach with both central procurement mechanisms such as the GDF and specific national-level strategies.

1. World Health Organization. Global TB Report 2019.
2. Data on file. Macleods Pharmaceuticals.
3. Dodd, et al. *Lancet Infect Dis*. 2016;16(10):1193–201.

A Closer Look at STEP-TB

Karachi, Pakistan

TB is a family disease, as it can be passed by a cough or sneeze. Families often live in close quarters, where one sick person can put many at risk.

One child in this family of eight was diagnosed with TB and was successfully treated with the child-friendly medication.

The family was so happy with how easy it was to give their child the dispersible tablets that they all returned to the clinic to be tested.

– Global Health Directorate, Indus Health Network

Nairobi, Kenya

In 2016, Chelsea's grandmother noticed that she was coughing, losing weight and was having trouble breathing regularly. Her grandmother brought her to a hospital in Nairobi where Chelsea was diagnosed with TB. She immediately started treatment.

Chelsea was among the first to receive child-friendly TB medicines before the national rollout. Two days after starting treatment, Chelsea could feel a difference.

She has now completed her treatment and is cured. She is an active and healthy girl.

– Centre for Health Solutions - Kenya (CHS)

Port Moresby, Papua New Guinea

In 2016, children in Papua New Guinea were disproportionately affected by TB – accounting for approximately 25 percent of identified cases nationally. In 2018, children represented about 11 percent of TB cases in the country.

Before the child-friendly medicines were available, children and caregivers had to mix and match different formulations to guess the correct dose for each child. With the support of the Australian Department of Foreign Affairs and Trade and the Louder Than TB campaign, child-friendly medicines are now available and childhood TB is getting more attention.

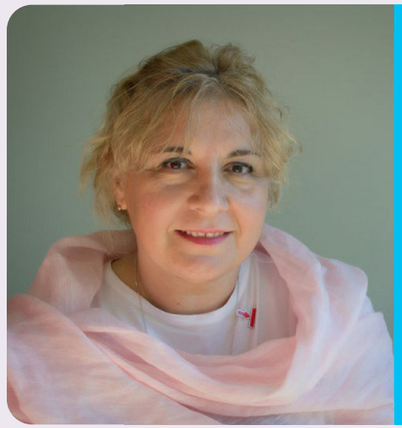
– Port Moresby General Hospital

Stakeholder Voices

Unitaid

"Child-friendly TB medicines are an excellent example of what we can achieve when we work together. At Unitaid, we are thrilled to have laid the foundations for governments and partners to bring these life-saving drugs to children in 93 countries."

– Lelio Marmora, executive director of Unitaid



Stop TB Partnership

"Reaching the milestone of one million ordered child-friendly TB treatments is fantastic, and the result of tremendous efforts from many partners. I want to highlight the part we did because as much as 98% of the ordered treatment courses were procured through StopTB Partnership's Global Drug Facility (GDF), using funds provided by USAID, Global Affairs Canada, the Global Fund as well as domestic budgets. In addition to GDF playing a key role in product introduction through technical assistance, our work with communities, civil society, and country partners ensured increased demand at the country level. Now, let's move on to achieve the next one million orders of child-friendly TB treatments."

– Lucica Ditiu, MD, executive director of the Stop TB Partnership

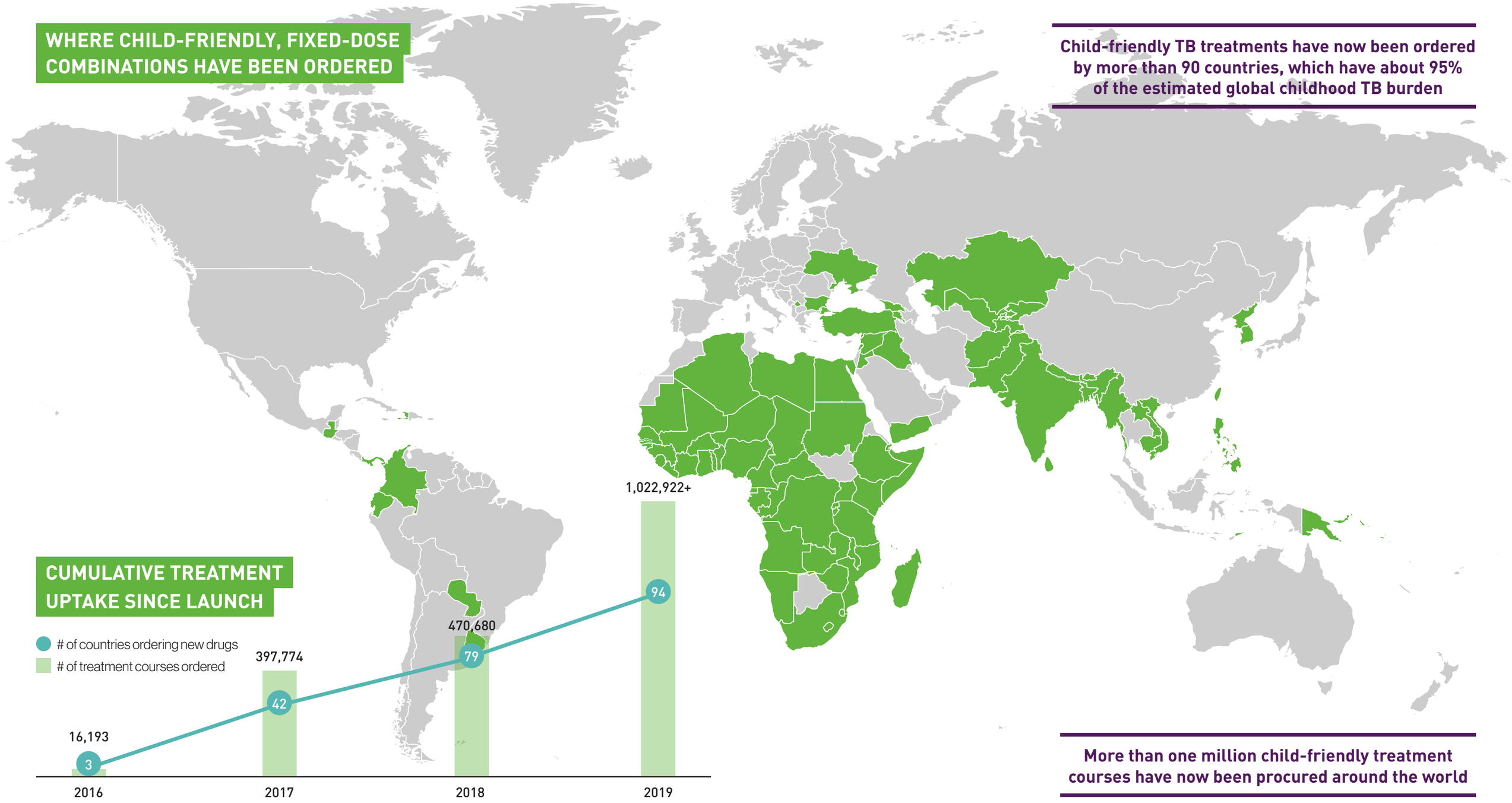
World Health Organization

"The World Health Organization is very pleased to see the successful roll out of the child-friendly FDCs that are ensuring that children receive the right doses of medicines, increase adherence and treatment outcomes, ease the burden on families and save more lives."

– Tereza Kasaeva, MD, director of WHO Global TB Programme

WHERE CHILD-FRIENDLY, FIXED-DOSE COMBINATIONS HAVE BEEN ORDERED

Child-friendly TB treatments have now been ordered by more than 90 countries, which have about 95% of the estimated global childhood TB burden



CUMULATIVE TREATMENT UPTAKE SINCE LAUNCH

of countries ordering new drugs

# of treatment courses ordered

More than one million child-friendly treatment courses have now been procured around the world

Data provided by Macleods Pharmaceuticals

TB Alliance | 20 YEARS OF IMPACT

40 Wall Street, 24th floor
New York, NY 10005
+1 212 227 7540

tballiance.org