

Barriers to Compassionate Use of Medicines for Drug Resistant-Tuberculosis

When emergency access becomes essential

Anita Mesic MD MSc PhD
Scientific Fellow, TB Unit, Clinical Science Department, ITM Antwerp
TB Advisor, Medecins Sans Frontiers

amesic@itg.be

22 June 2026



**INSTITUTE
OF TROPICAL
MEDICINE
ANTWERP**

The problem: resistance outpaced treatment

- DR-TB once marked by long, toxic, poorly effective regimens
- New medicines transformed treatment: shorter –safer – effective
- Progress does not mean the problem is solved
- Resistance continues to emerge
- People with highly resistant TB may again face limited options
- Innovation cannot be a one-time success, it has to continue
- Promising investigational compounds advancing, **but access remains years away**

Scientific progress needs to be matched by timely and equitable access.

When resistance closes every door

“After two years of treatment, a woman in Myanmar learned that her TB was resistant to all drugs used in current DR-TB regimens. She hopes for a cure, but cannot afford to wait for new medicines. Her greatest fear is passing this highly resistant disease to her children. She asks for one thing: timely access to life-saving treatment.”

>7%

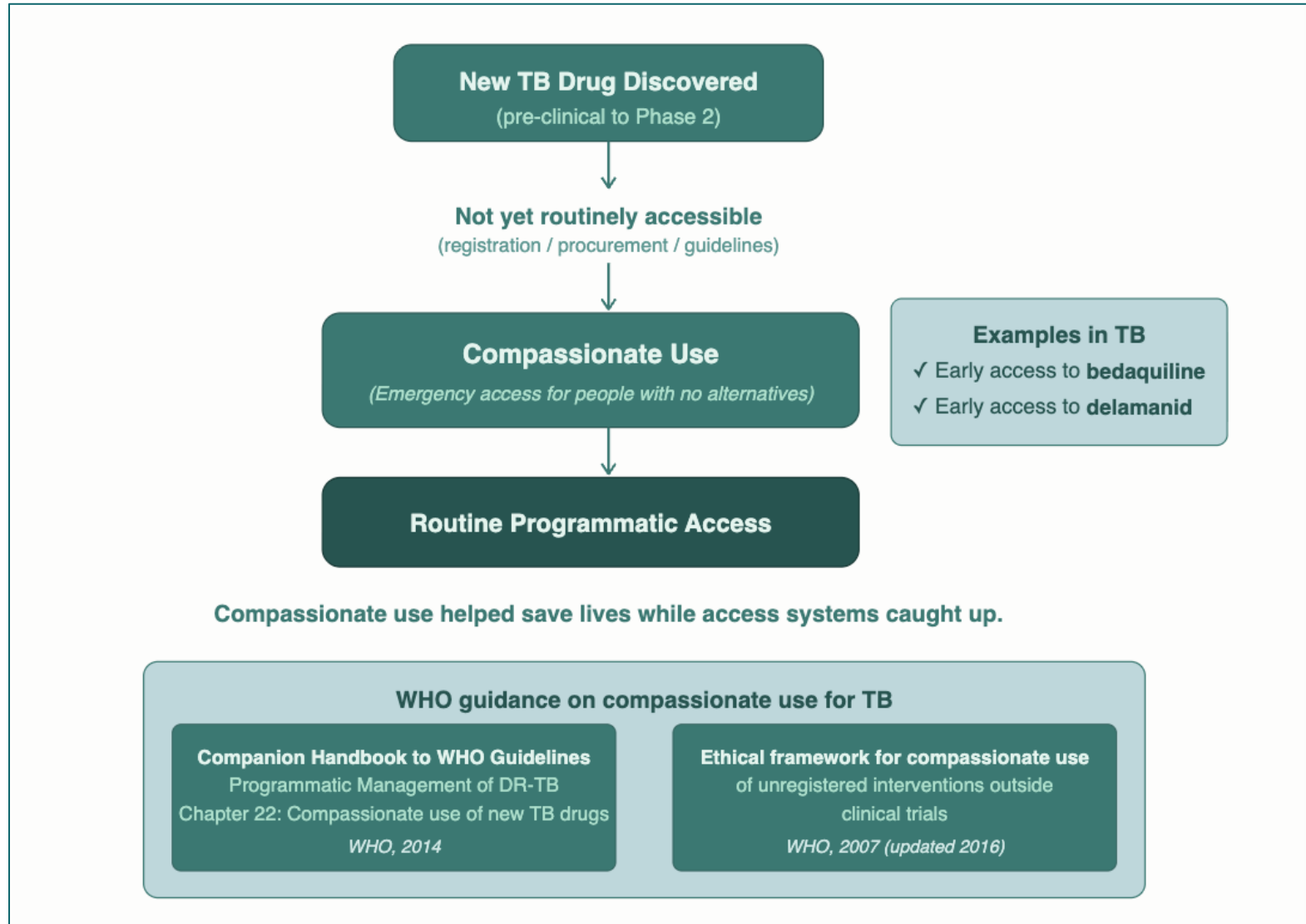
Baseline bedaquiline resistance in some high-burden settings

<40%

Treatment success for XDR-TB in Europe;
~1 in 3 people dies during therapy

*Hu et al., BMC Infect Dis, 2025
Kherabi et al., Lancet ID, 2025*

Compassionate use: bridging innovation and access



Multiple barriers to compassionate use

1. Regulatory fragmentation

- Multiple approval layers
- Administrative burden
- Complex or non-existing pathways
- No standard timelines
- Unclear procedures

Each step may be reasonable: together, they can make timely access impossible.

2. Inequitable access

- Unequal capacity across settings
- Lack of expertise
- Import and logistics barriers

Those with greatest need face greatest barriers

3. Commercial

- Manufacturer participation
- Legal and liability concerns
- Supply, legal challenges
- Internal policies
- Lack of transparency

Clinical need may not guarantee access

Compassionate use is not governed by a single coherent global framework

The access–evidence paradox



Clinical reality

- Patients with urgent unmet need cannot wait
- Highly resistant TB cases may have few alternatives

How do we balance access, safety, and evidence generation?

Is TB an exception?

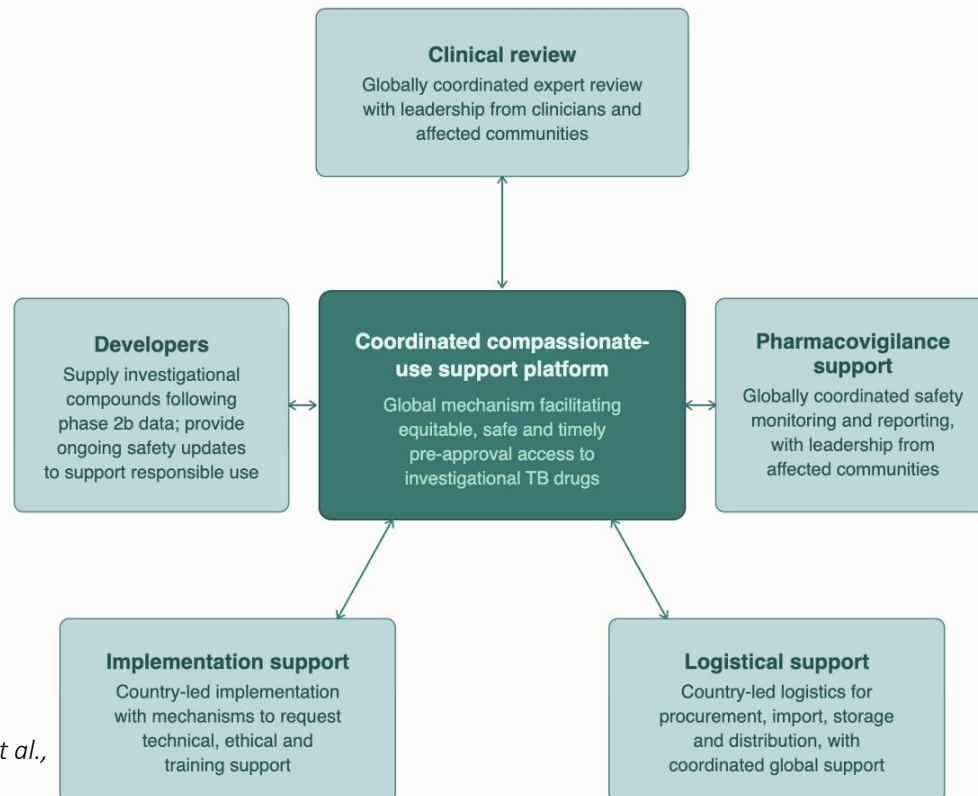
TB is the warning signal.

- Structural weaknesses familiar across global health
- People with cancer, rare diseases, AMR, and in outbreaks similar barriers
- Complex approval pathways delay access to promising therapies
- The consequences are predictable: people die while waiting for drugs that could save their lives.

➤ Urgent need requires urgent pathways

Compassionate Use Support Platform (CUSP)

A globally coordinated mechanism to facilitate equitable, safe and timely pre approval access to new TB drugs: bridging developers, regulators, NTPs, clinicians and affected communities.



Shared responsibility:

Access not dependent on goodwill of a single developer or the regulatory capacity of a single country:

- **Developers:** Urgency, openness, compassion
- **Regulators:** Create pathways, not obstacles
- **Donors:** Sustained support
- **Governments:** Dedicated budgets
- **Communities:** Advocate for equity and accountability
- **Researchers:** Outcomes not just academic outputs but as accountability

Beyond TB: A generalizable framework

- CUSP applicable **beyond TB**: to any disease requiring pre-approval drug access regardless of geography
- Core components **disease-agnostic** and adaptable
- The **same structural barriers** to access exist across many disease areas
- **Shared platform** reduces redundancy and builds on experience
- **Broader adoption**: strengthens national and global preparedness for future

Compassionate use is not a privilege: it is a test of whether global health systems can deliver on the promise of equity.