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Access to medicines for neglected tropical diseases including during the pre-elimination phase: the case of visceral leishmaniasis

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Visceral leishmaniasis (VL): current burden & key drugs

- East Africa: ~ 80%
- Indian subcontinent: ~ 5%
- Brazil: ~ 10%

- VL elimination program Indian subcontinent
  - Miltefosine → liposomal amphotericin B (AmBisome®)
- VL elimination program East Africa
  - First line: miltefosine and paromomycin
  - Alternative: paromomycin and pentavalent antimonials
  - Second line/special groups: AmBisome (+ miltefosine - HIV), Pentamidine (secondary prohylaxis of HIV-VL)

Key drugs

- AmBisome
  - Donation program by Gilead until 2030
- Miltefosine
  - 2 generics WHO pre-qualified
- Paromomycin
  - Single producer, minimal ordering quantities, case of batch problem
- Antimonials: mainly sodium stibogluconate (SSG)
  - Single producer
- All first-line anti-leishmanials are included in WHO Model List of Essential Medicines

Central role of WHO - challenges

- Multiple drugs, producers
- For some single producer: risky cfr ITLEISH RDT
- Minimal ordering requirements: more concerning in pre-elimination era → no business case?
- Widely spread over multiple countries
- Donation only for one drug (AmBisome®)
- All procurement and financing (except AmBisome ®) by WHO (EndFund)
- Limited innovation
  - Paromomycin, LXE408
- Child friendly?
  - Only miltefosine oral drug (negation for generics)
- Drug registration in endemic countries, limited PV

Key points

- Current drugs suboptimal (toxicity, complex…)
- Not child friendly
- Limited innovation (and R&D actors)

- Complex set-up (multiple drugs/one donation) – vulnerable supply
- Some (supply) problems might increase in the pre-elimination phase

- The case of VL is representative of other NTDs
  - Insufficient R&D
  - Fragile supply
  - Lack of children-friendly tools
  - Increased supply fragility in pre-elimination phase, with reduced and scattered demand