Fast-tracking development and introduction of paediatric ARV formulations: Framing the rationale

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Paeds Drug Optimization

Key consultations have advanced the discussion on drug and formulations development for children and resulted in a more collaborative and coordinated action.
Developing and delivering paediatric formulations through collaborative and coordinated action

Key formulations are prioritised in the context of a public health approach.

Technical/research work is undertaken to support development of the priority formulations.

Priority formulations are included in optimal formulary for selection.

Priority formulations are procured via a pooled mechanism.

Priority formulations are reliably supplied to countries.

Drug optimization

PADO

PAWG

PHTI

IATT

PAPWG

PROGRAMS
LPVr 4-in-1: first line for under 3 years to address the lack of optimal formulations

EFV triple: first line 3-10 years to provide an FDC to maximise adherence and simplify procurement

ATVr and DRVr: use in 2nd and 3rd line formulations and overcome issue with separate administration of RTV

NVP/AZT mg: better dosage form to facilitate dosing for PnP

RAL better formulation: use in infants and young children to enable rapid introduction of INI for use in 1st line regimen

DTG single or FDCs: identified as key drug to introduce INI in first line with potential for harmonisation across the full age spectrum

TAF: key drug for future use in 1st line to minimise toxicity with potential for harmonization across the full age spectrum
Paediatric HIV Treatment Initiative (PHTI)
Evolving dialogue

- CTA bottle neck analysis highlighted in 2015 the need to think about alternative financing mechanisms
- EMEA meeting on paediatric ARV formulations
- CROI meetings advanced our thinking
- ILF roundtable (kick-off the conversation)
- Bilateral conversations lead by CTA partners
  - Regulators
  - Research networks
  - Industry
The Global accelerator for Paediatric formulations

FAST-TRACKING DEVELOPMENT OF PAEDIATRIC ARVS

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World Health Organization
The Global accelerator for Paediatric formulations

This is NOT a new initiative!

The Global accelerator is an innovative financing mechanism in support of a collaboration framework to fast track development of paediatric formulations.

This collaboration framework builds on existing efforts and aims to promote a faster, more efficient and more focused approach to paediatric formulation development.
Thank you