



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Expert meeting on paediatric development of fixed-dose combinations for the treatment of the human immunodeficiency virus (HIV)

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Way forward

- Some FDCs to be prioritised down to the youngest age.
- Age cut-off for the waiver request to be defined as low as possible, (prevention of HIV ?)
- The clinical development in the paediatric age range should take place as early as possible relative to the adult development unless there are specific safety concerns from the preclinical data or clinical data that may justify delaying the paediatric development. If no particular concerns were present, the development for adolescents and adults as well as for children down to the age of 2 years should not be delayed.
- Development of an age-appropriate paediatric formulation to be started as early as possible taking into account the final age cut-off.
- Dosing recommendations to be based on body weight rather than on age. For both single agents and FDC the use of WHO weight bands is encouraged.