Stage 1 Actions

1. FDA/EMA initiative to impact faster pediatric studies – WHO, in collaboration with other relevant CTA partners to set up meetings with the FDA Division of Antiviral Products and the EMA PDCO to discuss and agree on ***three to five key recommendations*** to innovators
2. FDA/EMA should guide the innovators to simplify and harmonise the PSP/PIP document
3. Develop a "master protocol" for pediatric clinical trials of ARVs designed to collect similar (required) PK and safety data for any desired pediatric product
3. WHO will further engage with strengthening the paediatric regulatory network and to promote a more coordinated approach to in-country drug registration
4. Explore the possibility of including additional incentives for pediatric formulation development when granting license for novel drugs.
5. Improve assessment of market needs and the staging/duration of each PADO priority product in the marketplace.

Stage 1 Actions (cont'd)

1. FDA/EMA initiative to impact faster pediatric studies – …to discuss and agree on ***three to five key recommendations*** to innovators
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- simplified, efficient pediatric trials

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6. Improve assessment of market needs and the staging/duration of each PADO priority product in the marketplace.

Stage 2 Activities

- Engage with the innovators and paediatric HIV **clinical trials networks** early on at the design stage of the initial paediatric studies
- **Incentivize generic** development of priority products as needed.
- Ensure **timely notification** of optimal FDCs recommended by PADO, including an ongoing assessment of order of priority.
- Promote **earlier collaboration between innovators and generics** so that the generics can potentially be part of innovator's development team and take up some of the work on early formulation development.
- Characterize and triangulate the **future demand for priority products**. Coordinate with various organizations involved in forecasting, including WHO, UNAIDS, CHAI, MPP, The Global Fund, PEPFAR and Department of Health of South Africa.
- Initiate **demand generation** activities during development.
- Work with country partners for developing and **rolling out scale-up** plans.
- Create a formulation **technology development platform**.