

January 29, 2018

Update January 2018

Dear Participants of the Rome High-Level Dialogue on Pediatric Formulations and Diagnostics,

In Rome we committed as co-chairs of the AIDS Free Working Group to keep participants regularly informed of developments related to the Action Plan. We're pleased to let you know that implementation has gotten off to a strong start, with stakeholders taking a variety of steps to follow through on their commitments, as well as to promote or facilitate the completion of actions by others. It is clear that the enthusiasm expressed by so many people in Rome for greater focus, acceleration, and collaboration is quickly translating into concrete actions. On our side, we have put together a small task team made up of representatives from EGPAF, PEPFAR, WHO, and the World Council of Churches (WCC-EAA) that will be responsible for proactively monitoring progress on the Action Plan and working with the AIDS Free Working Group (AFWG) on those actions committed to by the AFWG co-chairs.

Please find below a summary of recent activities reported to us. We would be grateful if you could keep us informed of any additional or planned activities so we may report on them to the wider group.

FOCUS

- Action 1: WHO convened a virtual meeting of the Pediatric ARV Drug Optimization (PADO) group in December to review the list of PADO3 pediatric ARV formulations and develop implementation considerations related to current priority products. Two webinars for dissemination of the key outcomes to manufactures and key stakeholders will be organized on February 5th by ILF/IAS in collaboration with WHO.
- Actions 2 & 4: WHO is working towards holding a Guidelines revision meeting during the week of April 30th to review 1st and 2nd line regimens for neonates, infants and children, potentially including integrase inhibitors for first line use. Revised guidelines should be made publicly available at IAS in July. Plans are to update the ARV Optimal Formulary in May to ensure full alignment with any potential guidelines change that may occur.

ACCELERATE

- Actions 18 and 22: GAP-f partners have been discussing with ViiV and regulatory authorities to determine the best regulatory pathways for pediatric DTG (10 mg scored and 50 mg scored tablets) and ways to accelerate registration and introduction of DTG and RAL at country level. In November, CHAI issued in collaboration with ViiV an

RFP for development of generic pediatric formulations of DTG, with the announcement of manufacturers selected expected in February.

- Action 20 and Additional commitment #1: In a letter to PEPFAR, FDA reiterated its general acceptance of the principles agreed in Rome to accelerate successful completion of pediatric plans (see attached letter). They should be communicated formally in the near future. WHO reached out to EMA to determine their interest in committing to similar rules.
- Action 24: PAWG is developing a toolkit to support manufactures and stakeholders involved in pediatric ARV development to ensure accelerated research, development, and introduction of priority pediatric formulations. A first draft of the toolkit, developed by WHO in collaboration with UNITAID, IMPAACT, PENTA and other key stakeholders, will be shared with manufactures and regulators for review in the next couple of months and final version will be made available in July 2018.

COLLABORATE

- Action 40: GAP-f will develop an updated concept note and business plan by IAS, and will soon establish a website to facilitate the sharing of resources on pediatric formulation research, development, and introduction (more details can be found in the attached update)
- Action 41: PEPFAR will organize a technical meeting in early February to share best practices and discuss new other strategies for identifying children living with HIV, particularly around finding well children and around looking beyond traditional, facility-based settings. WHO, EGPAF, PEPFAR, and WCC have begun discussions on one or more additional meetings on pediatric diagnostics in Q2 of 2018.

Additional commitments:

3. CHAI has developed draft plans to accelerate in-country uptake of new pediatric ARVs in collaboration with other stakeholders.

5 and 7. PEPFAR has been in touch with ViiV and Merck about their commitments to make pediatric drugs available to LMIC. The companies confirmed their intention to provide them at access pricing until generics were available, and potentially beyond.

9. Mylan submitted its pediatric LPV/r formulation to WHO PQ in December, and is now working on submitting to the Global Fund ERP. It plans to submit to FDA shortly.

Best regards,

Gottfried Hirschall, WHO and Chip Lyons, EGPAF

Co-Chairs, AIDS Free Working Group

