



## CTA Meeting on Paediatric ARVs: Introducing the Global Accelerator for Paediatric Formulations

Monday, 5 December 2016, 17:00-21:00 CET  
Rooms Dornier/Douglas, Mövenpick Hotel, Geneva (Switzerland)

On 5 December 2016, the Global Pediatric Antiretroviral Commitment-to-Action (CTA) partner organizations<sup>1</sup> will convene key stakeholders in the paediatric ARV space to accelerate joint efforts to identify innovative approaches to fast-track development and introduction of priority paediatric formulations. This meeting will build on previous efforts to develop a collaborative framework to accelerate development of paediatric ARVs, and, potentially, serve as a model for tuberculosis and other disease areas.

Most recently, in July 2016, the partners convened a workshop ahead of the 21<sup>st</sup> International AIDS Conference in Durban, South Africa<sup>2</sup>. In the context of existing broader constraints to paediatric ARV development, participating stakeholders agreed on the need for a range of actions, including:

- Reviewing the current age-staggered approach for development of new products in order to include adolescents in initial (registrational) adult efficacy trials and promote simultaneous enrolment of children in different age groups
- Developing age-appropriate paediatric formulations earlier in the process of testing new drugs in adults in order to minimize the paediatric formulation development and approval timelines
- Improving the collaboration and alignment between regulatory authorities
- More systematic coordination between regulators, industry and research networks during the development and review of paediatric implementation plans (PIPs) and pediatric study plans (PSPs)
- Simplifying the PIP/PSP modification processes
- Encouraging other regulators to recognize and act on Paediatric ARV Drug Optimization (PADO) priorities to speed up in-country introduction
- Increasing information sharing, especially for PADO deliberations, to industry and regulators
- Exploring alternative options to leverage generic industry engagement and potentially provide assistance to PIPs/PSPs
- Developing incentives to stimulate paediatric formulation development by targeting the steps of biggest concern (e.g., financing clinical trials, trials in-country registration, and demand creation and consolidation).

Stakeholders also agreed that the proposed framework could be a useful mechanism for supporting accelerated paediatric ARV development. Industry representatives noted that while

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<sup>1</sup> Consisting of the International AIDS Society (IAS), World Health Organization (WHO), the Clinton Health Access Initiative (CHAI), the Drugs for Neglected Diseases initiative (DNDi), the Medicines Patent Pool (MPP), UNITAID, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and the Global Fund to Fight AIDS, TB and Malaria (Global Fund).

<sup>2</sup> The report for the *CTA/ILF/CIPHER Thematic Roundtable on Paediatric ARVs: Fast tracking development of priority formulations* is available at: <http://bit.ly/2f9GXkl>.



lack of funds to develop paediatric ARVs may not be the only limitation as long as drugs are purchased once developed, financial support may be required for other steps in the cascade from research to development to introduction.

The 5 December meeting will move this conversation forward. The objectives of the meeting are to first assess the level of stakeholder support for the revised proposal for a Global Accelerator for Paediatric Formulations and, second, provided the framework is supported, to identify and generate consensus around key action steps required for its implementation. To that end, the CTA will convene leaders from across the HIV community and after presenting the revised framework, two panel discussions will help better define some of the concrete steps to be taken in order to start implementing the principles of the Global Accelerator for Paediatric Formulations, at global as well as at country level.

The first panel will focus on specific actions the global community can take to accelerate the development, production and registration of priority paediatric ARVs. Particular attention will be given to how the collaborative framework put forth through the proposed global accelerator could affect the roles and activities of pharmaceutical companies (generics and innovators), stringent regulatory authorities, institutional review boards, development partners, and civil society organizations, operating at the regional or global level. The second panel will discuss specific activities that can be taken by key country actors to expedite registration and uptake and increase demand for high-priority paediatric ARVs in-country. Panel participants will discuss the roles of country regulatory agencies, as well as of global partners working in countries. They will also elaborate on how the global accelerator could improve coordination of activities to ensure that barriers to uptake are minimized, demand is generated, and priority products are taken up sooner.

Key considerations shared during the meeting will be summarized and used to inform the next steps to be taken during the first phase of implementation of the Global Accelerator for Paediatric Formulations.

We are delighted to invite you to this meeting on the evening of Monday, 5 December, in Geneva (Switzerland). Please confirm your participation to Helena Edmonds (HIV Programmes Intern, IAS) at [helena.edmonds@iasociety.org](mailto:helena.edmonds@iasociety.org).

Thank you for your interest. Best wishes,

CTA partners

### ***About the Global Pediatric Antiretroviral Commitment-to-Action***

*The Global Pediatric Antiretroviral Commitment-to-Action (CTA) was launched on World AIDS Day 2014. It is composed of the World Health Organization (WHO), the Pediatric HIV Treatment Initiative (PHTI, which includes UNITAID, the Clinton Health Access Initiative – CHAI, the Drugs for Neglected Diseases initiative – DNDi, and the Medicines Patent Pool – MPP), the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, TB and Malaria (Global Fund), and, since 2016, the International AIDS Society (IAS), through its Industry Liaison Forum (ILF).*