

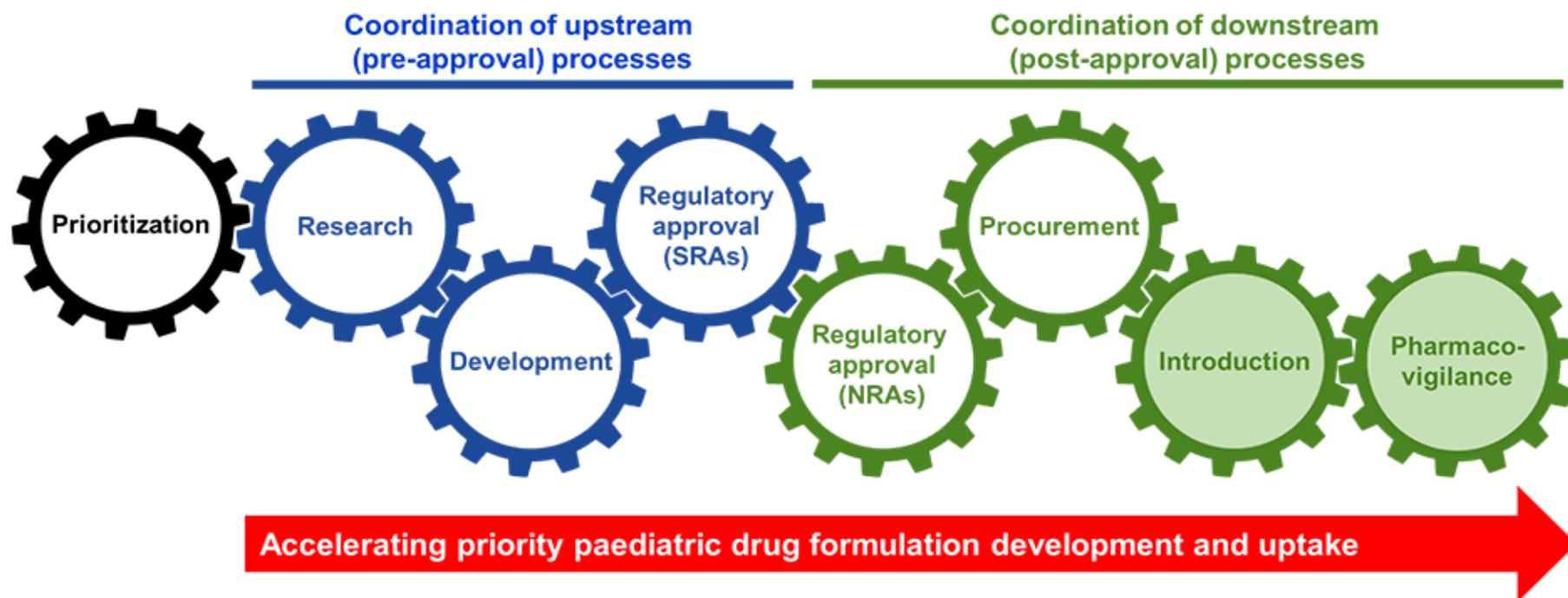


Toolkit for research and development of paediatric antiretroviral drugs and formulations webinar series

Webinar 5: Pregnant and breastfeeding women

30 November 2018, 14:00-15:30 CET

The GAP-f formalizes collaboration across sectors to ensure accelerated development and uptake of the most needed drugs and formulations for children.



AIDS 2018 satellite on “Accelerating the development and uptake of the most needed drug formulations for children”

See slide sets and watch the recording at

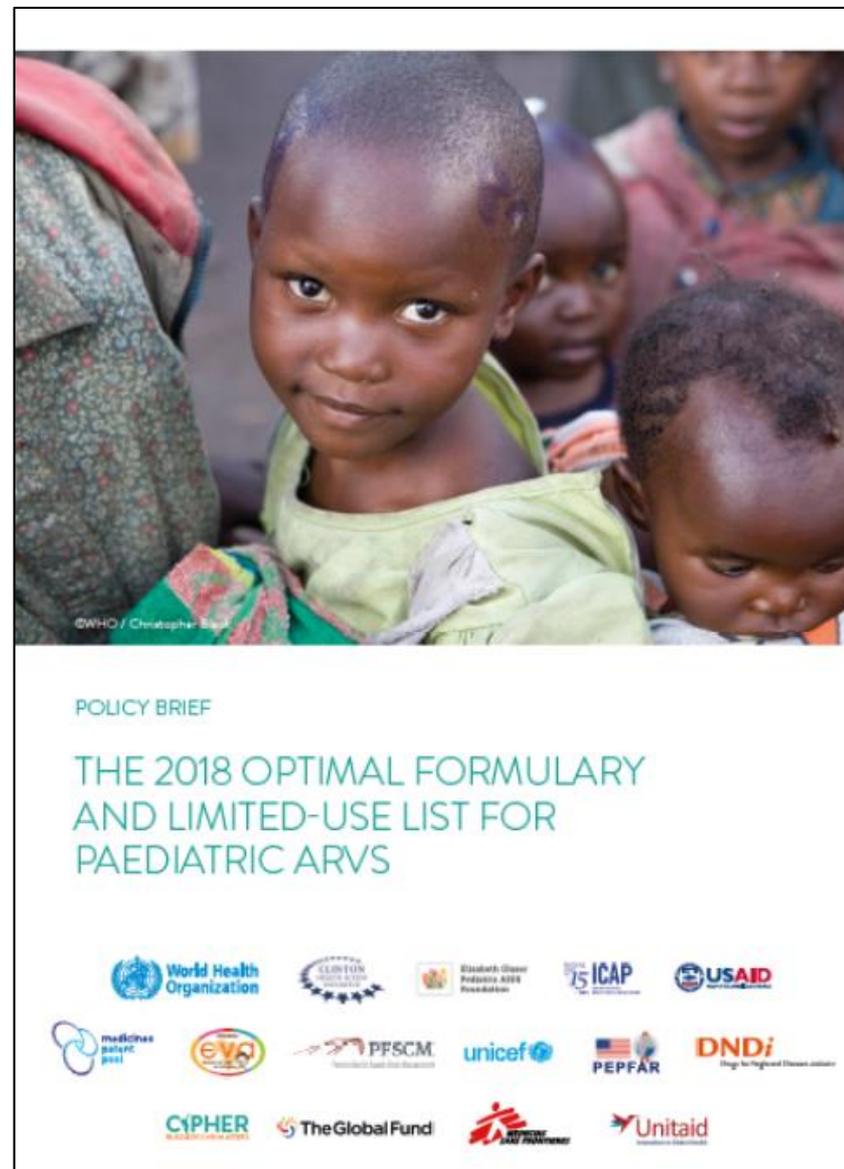
<http://programme.aids2018.org/Programme/Session/1484>



GAP-f is accelerating existing work:

2018 Optimal Formulary and Limited-Use List for Paediatric ARVs

Read the policy brief [here](#)



POLICY BRIEF

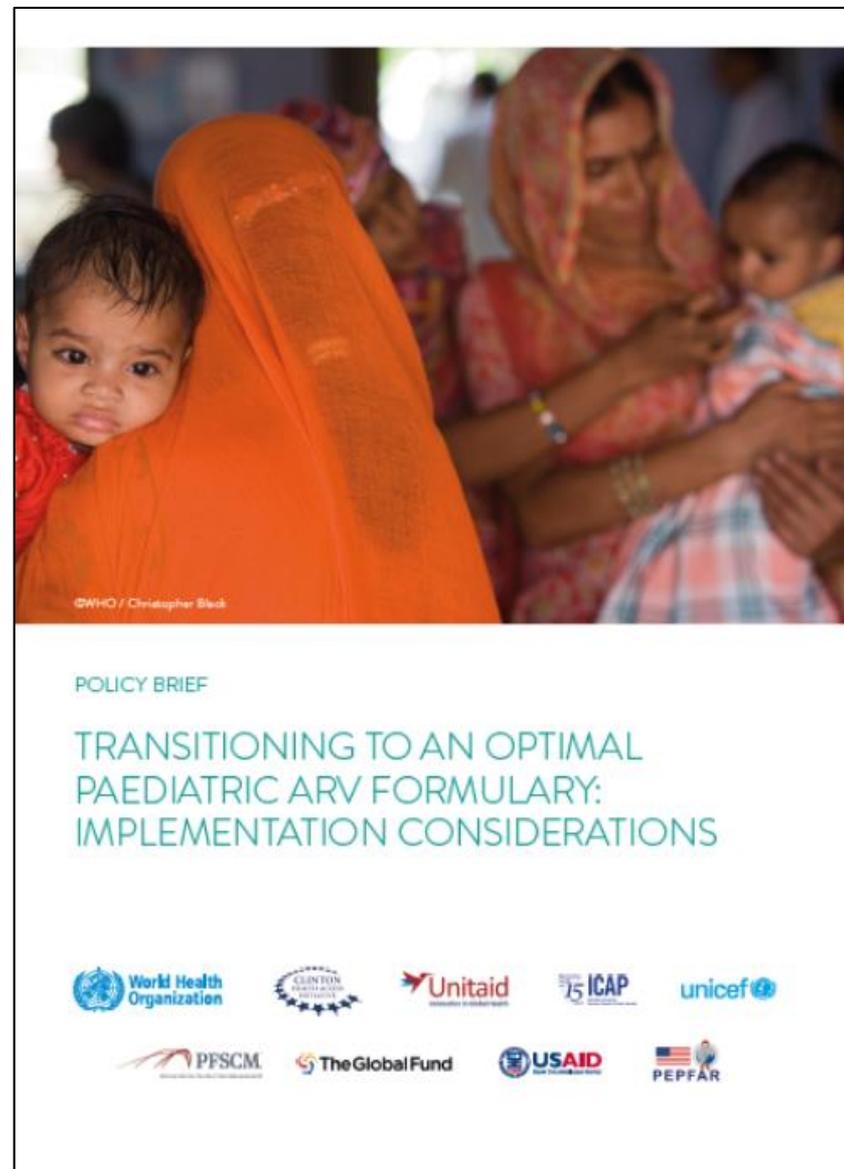
THE 2018 OPTIMAL FORMULARY
AND LIMITED-USE LIST FOR
PAEDIATRIC ARVS

World Health Organization
CLINTON FOUNDATION
Elizabeth Glaser Pediatric AIDS Foundation
ICAP
USAID
medicines patent pool
EVA
PFSCM
unicef
PEPFAR
DNDi
CIPHER
The Global Fund
Unitaid

GAP-f is accelerating existing work:

Transitioning to an optimal paediatric ARV formulary: implementation considerations

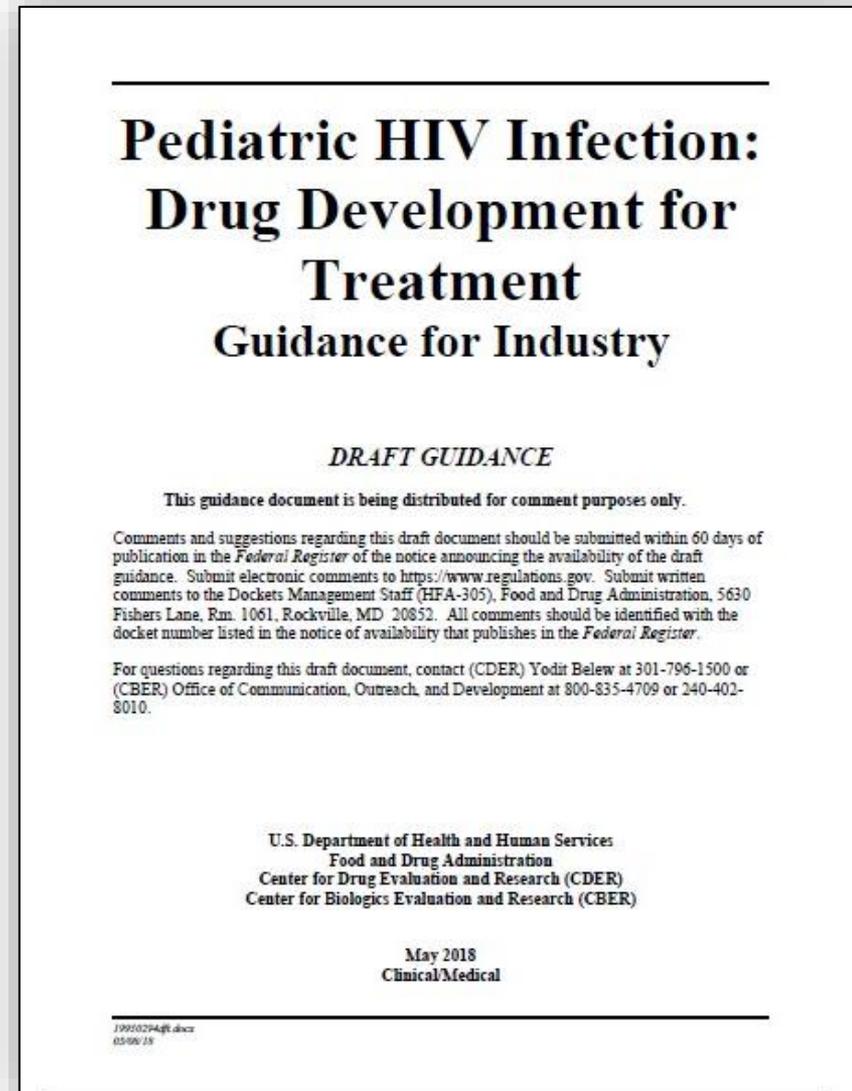
Read the policy brief [here](#)



GAP-f is already delivering:

Draft FDA guidance for industry on pediatric HIV infection: Drug development for treatment

See the draft guidance [here](#)



GAP-f is already delivering:

Toolkit for research and development of paediatric antiretroviral drugs and formulations

Access the toolkit [here](#)

Access an online version with slide sets [here](#)



TOOLKIT FOR RESEARCH AND DEVELOPMENT OF PAEDIATRIC ANTIRETROVIRAL DRUGS AND FORMULATIONS

WHO and UNITAID

in collaboration with IMPAACT (International Maternal Pediatric Adolescent AIDS Clinical Trials) network, PENTA (Paediatric European Network for Treatment of AIDS) foundation and experts from the Paediatric Antiretroviral Working Group



Today's agenda

14:00 CET	Welcome and introduction Sébastien Morin (IAS, Switzerland)
14:05 CET	The toolkit: rationale and methodology Martina Penazzato (WHO, Switzerland) Claire Townsend (WHO, Switzerland)
14:15 CET	Pregnant and breastfeeding women – toolkit module <u>Angela Colbers</u> (Radboud University Medical Center, Netherlands) Mark Mirochnick (Boston University, USA)
14:30 CET	Safety and pharmacovigilance: challenges and opportunities Claire Thorne (University College London, United Kingdom)
14:45 CET	Bioethics: including pregnant women in HIV research Maggie Little (Georgetown University, USA)
15:00 CET	Stakeholder perspectives Leyla Sahin (Food and Drug Administration, USA) Maribel Gonzalez Tome and Corinne de Vries (European Medicines Agency, UK) Jacque Wambui (NEPHAK & AfroCAB, Kenya)
15:10 CET	Q&A Facilitated by Sébastien Morin (IAS, Switzerland)
15:25 CET	Closing remarks Martina Penazzato (WHO, Switzerland)

Key considerations: Compliance with competition rules

What to avoid

- **Do not** discuss with other participants competitively sensitive information on anything relating to topics such as prices, discounts, margins, price-related contractual terms or territorial protection.
- **Do not** exchange information on costs, capacity, business plans or commercial strategy. The only exception is for industry data that are publicly available via data services, such as interest rates.
- **Do not** exchange individualized information on output plans.
- **Do not** engage in conduct that could have the effect of restricting competition by excluding actual or potential competitors from the market or preventing them from competing effectively.
- **Do not** discuss matters relating to your company's marketing plans, design, production or distribution.
- **Do not** share with other participants any other competitively sensitive or confidential information.

What to do

- **Do** report to the IAS any discussion or conduct that you suspect might violate these guidelines, and keep a copy of such correspondence.
- **Do** leave any discussion that you feel might infringe these guidelines, and ask for your leaving to be recorded in the minutes.
- **Do** refuse any commercially sensitive or confidential information you might be offered. If you receive such information, return them immediately, emphasizing that you do not want to have access to them. Keep a copy of such correspondence.
- **Do** remember that you are responsible for your own compliance with these guidelines.

Read more at http://www.iasociety.org/Web/WebContent/File/ILF_Compliance_with_competition_rules.pdf