medicines patent pool

Medicines Patent Pool – Strictly Confidential, Not for Circulation

Paediatric HIV Treatment Initiative (PHTI). Overview presentation.

ILF/CIPHER Thematic Roundtable on Paediatric ARVs,

Geneva, March 18th 2015

Fernando Pascual and Sandeep Juneja

medicines patent pool

Scope

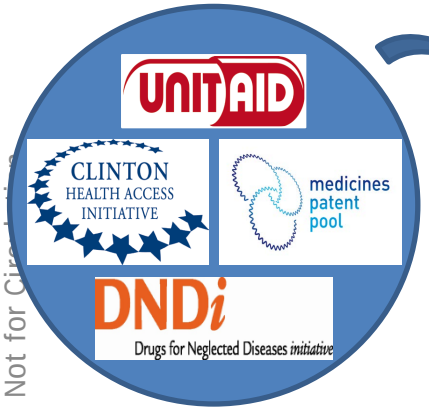
UNITAID convenes the key partners to join the **Paediatric HIV Treatment Initiative**, a dynamic platform for the exchange of information aiming creating synergies. The initiative builds upon and complement current and past initiatives and experience to:

- ➔ Ensure intellectual property and knowledge sharing
- ➔ Ensure technical guidance from WHO experts translates into real medicines
- ➔ Facilitate the financing mechanisms for the development, manufacture and market uptake
- ➔ Provide a platform for the different partners to work together

Medicines Patent Pool – Strictly Confidential, Not for Circulation

medicines patent pool

PHTI structure



Strategic and coordination support (*Coordinators* and *Strategy Group*)

Product Specific Team (PST)

Composition: experts, pharmaceutical companies, PHTI members

- Identify work needed to fill gap of formulation development
- Develop work plans, timelines, budget
- Ensure work from formulation to access is performed

Stakeholders

Reporting / feedback twice a year

Reporting and feedback quarterly

WHO, PADO

Alignment with WHO/PADO priorities

Medicines Patent Pool – Strictly Confidential, Not for Circ

medicines patent pool

PHTI update

- Launch: Geneva May 19th and in the US in June17 th, 2014.
- Strategy Group meetings: decision on operational framework, phases in product delivery and next steps
- Presented to stakeholders during a meeting in Melbourne during the AIDS2014 Conference (over 60 participants: industry, financing organizations, civil society, research organizations, National programs…)
  - Overview of operational framework
  - Stakeholders committed to participate on product delivery upon request
  - Satellite meeting: AIDS2014 Conference

Medicines Patent Pool – Strictly Confidential, Not for Circulation

medicines patent pool

PHTI update

- ABC/3TC/EFV project
  - Technical working group set
  - Development plan drafted
  - Invitation for Expression of Interest to select generic partners published
- DRV/r project
  - Technical working group (March 16th)
- Stakeholders meeting set (April 8th)

➔Product specific teams already drafting product development plans with timelines and deliverables

Medicines Patent Pool – Strictly Confidential, Not for Circulation

medicines patent pool

Rationale

There are 3.2 million children living with HIV, most of them in lower and middle income Countries (LMICs) today.

Treatment penetration in paediatric population has been slow: only 740,000 children on ART per latest data

PHTI aims to change this: better treatment for all kids, faster

Medicines Patent Pool – Strictly Confidential, Not for Circulation

medicines patent pool

Rationale

Reasons for the treatment gap

Perception of shrinking market
(35% decline in newly infected children from 2009 to 2012. Target zero new infections by 2015. Still around 1.5 million CLHIV in need of treatment by 2020)

↓

Lack of coordination among partners to boost development of appropriate formulations

↓

Uninteresting/fragmented market
(45 different formulations available, only 8 adapted)

↓

Lack of adapted formulations
(E.g.: LPV/r only as an unpalatable oral solution that requires refrigeration)

↓

Paediatric HIV is neglected

Medicines Patent Pool – Strictly Confidential, Not for Circulation

medicines patent pool

Rationale

Reasons for the treatment gap	Public health impact of PHTI
Perception of shrinking market (35% decline in newly infected children from 2009 to 2012.Target zero new infections by 2015. Still around 1.5 million CLHIV in need of treatment by 2020)	PHTI offers a viable business model for paediatric formulations thus attracting interest from industry
Lack of coordination among partners to boost development of appropriate formulations	PHTI creates platform for industry, drug development organizations, financing organizations, civil society…
Uninteresting/fragmented market (45 different formulations available, only 10 adapted)	Focus only on WHO priority products, thus contributing to rationalize the market
Lack of adapted formulations (E.g.: LPV/r only as an unpalatable oral solution that requires refrigeration)	Delivers adapted formulations
Paediatric HIV is neglected	Overall, it engages public health actors involved in paediatric HIV.

Medicines Patent Pool – Strictly Confidential, Not for Circulation

medicines patent pool

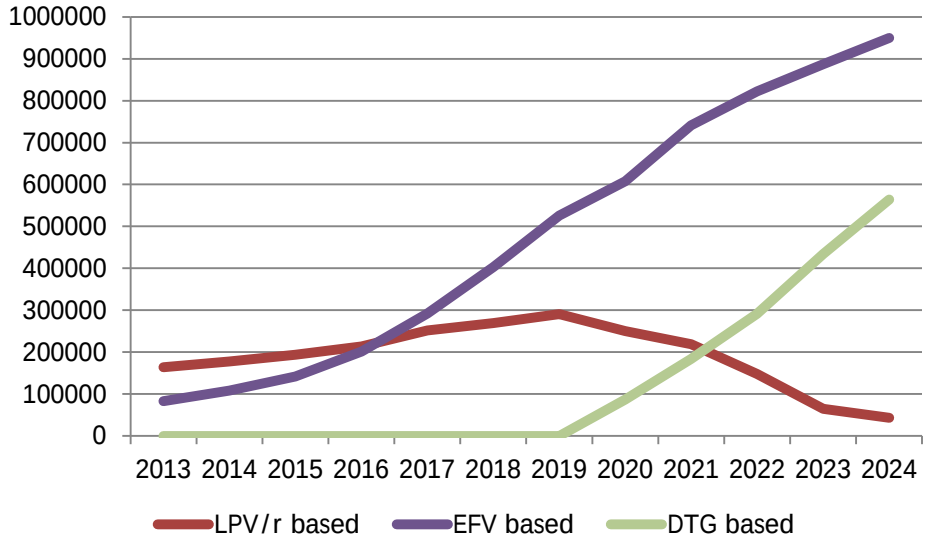
Priority products (PADO2)

PRIORITIES (as per PADO2)	Started	IP	Clinical/ dosing	Development/ manufacturing	Regulatory/uptake
ABC/3TC/LPV/r	Yes	Licensed to MPP	Done	Under way	Under way
LPV/r	Yes	Licensed to MPP	Done	Under way	Under way
ABC/3TC/EFV	Yes	Licensed to MPP	Done	Generics invited	Not yet
DRV/r	Yes	Assessing IP (*)	Under way	Not yet	Not yet
RAL	Not yet	Licensed to MPP	Under way	Not yet	Not yet
ATV/r	Not yet	Licensed to MPP	Not done	Not yet	Not yet
DTG/XTC/TAF	Not yet	Licensed to MPP	Not done	Not yet	Not yet
DTG	Not yet	Licensed to MPP	Not done	Not yet	Not yet

(*) Janssen has expressed support to the PHTI

Medicines Patent Pool – Strictly Confidential, Not for Circulation

Public health impact



- Impact in number of patients
- Also puts in place mechanisms to accelerate development and market uptake of products needed for smaller specific groups (e.g. DRV/r for patients failing to LPV/r)

Priority formulation	Clinical importance
ABC/3TC/LPV/r (30/15/40/10mg)	1st line in <3y and 2nd line
LPV/r (40/10mg)	1st line in <3y and 2nd line
ATV/r (100/33mg)	Alternative PI for 2nd line or 1st line in <3y
DRV/r (120/20mg)	Potential 2nd line. Only alternative after failure to LPV/r
ABC/3TC/EFV (150/150/75mg)	1st line in 3 to 10y
RAL	Less than 3y
DTG/XTC/TAF	Potential alternative to TDF and ABC (reduced bone and renal toxicity)
DTG	Potential 1st or 2nd line. Harmonization with adults.

Medicines Patent Pool – Strictly Confidential, Not for Circulation

medicines patent pool

Conclusions

- The PHTI works in close collaboration with WHO regarding priorities
- Will not result in further market fragmentation
- It pools resources and brings in experts from multiple agencies to work on different projects
- It allows leveraging high quality resources fairly quickly and working in several projects in parallel
- Great public health impact

Medicines Patent Pool – Strictly Confidential, Not for Circulation