UPDATE ON PHTI PROJECTS

REPORT BACK FROM THE PAEDIATRICS WEEK

December 15th, 2016

PHTI structure

IP/data

Address patent-related issues and license management

Medicines Patent Pool

Quality/regulatory/technical recommendations

Inform developers of expected needs for review; prioritize review as product becomes available

WHO

Development

Develop and validate infant-friendly formulation of ABC/3TC/ LPV/r

DND*i*

Optimize regimens for children according to PADO recommendations

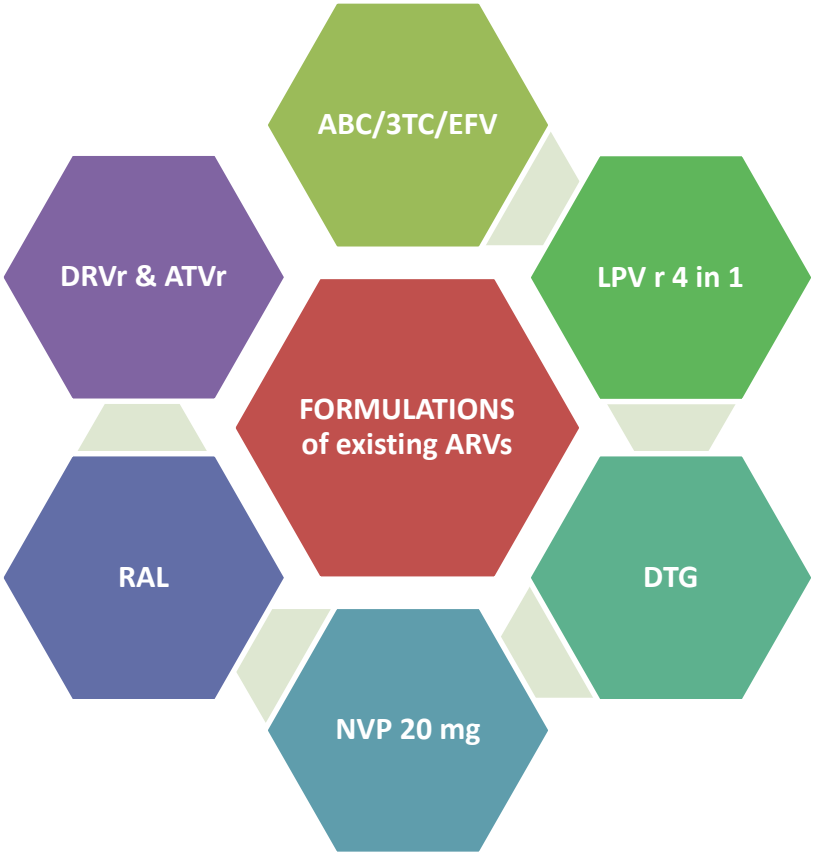
Procurement

Market shaping and preparation

CHAI and ARV Procurement Working Group

Coordination (UNITAID)

PADO 2 priorities

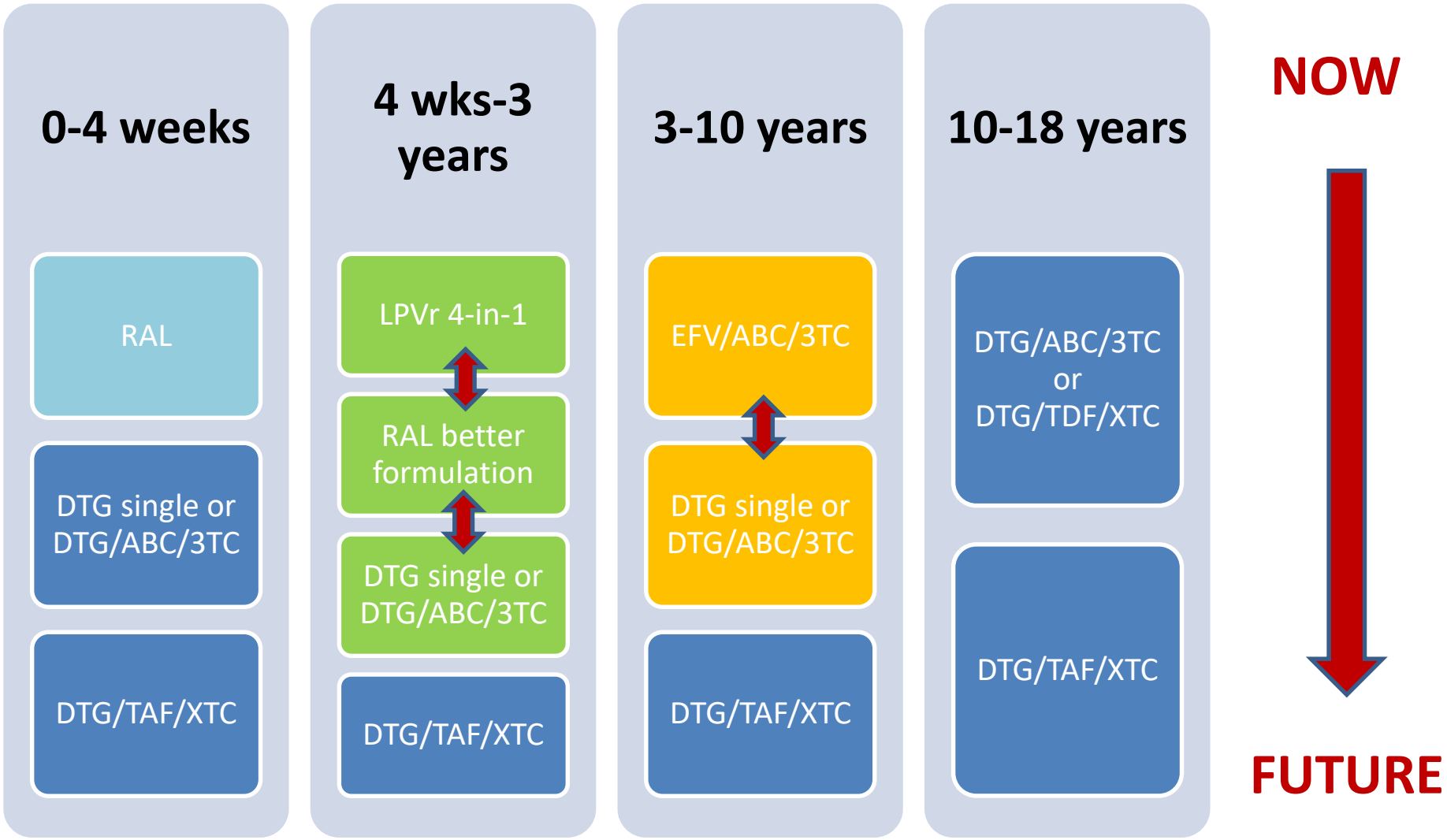


Identifying priorities regimens for optimal sequencing which include **newer compounds** for which paediatric development has not been completed

New formulations of **existing drugs** that already have registration for children or in advanced paediatric development

	0-3 yrs	3-10 yrs	10 yrs +
FIRST LINE			
Mid-term (5 yr)	ABC/3TC/DTG		TAF/3TC/DTG
Long term (10 yr)	TAF/3TC/DTG		
SECOND LINE			
Mid-term (5 yr)	AZT/3TC/RAL or LPV/r	AZT/3TC/DRV/r	TAF/3TC/DRV/r
Long term (10 yr)	AZT/3TC/LPV/r	RPV/DRV/r or AZT/3TC/DRVr	

Treatment sequencing



PHTI structure

PRODUCT	FORMULATION	LEADER IN PHTI
ABC/3TC/LPV/r	30mg/15mg/40mg/10mg granules	DNDI
ABC/3TC/EFV	150mg/75mg /150mg dispersible tablets	MPP
RAL	50mg scored dispersible tablet (25mg chewable or 50mg chewable also possible)	MPP
DRV/r	120/20 mg tablet	CHAI
DTG-based formulations	Various strengths	CHAI

Licensing

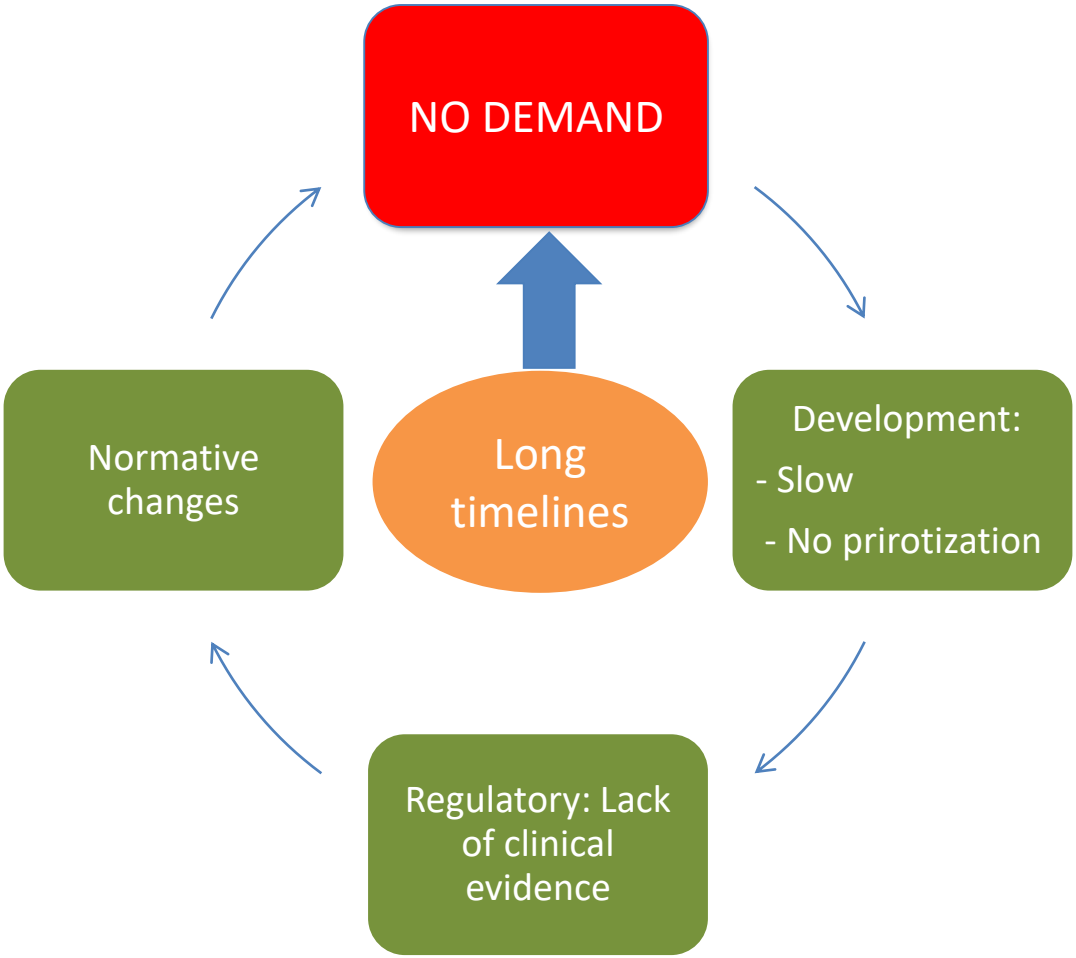
All currently recommended paediatric **and some new** ARVs have been licensed by the originator:

- ABC
- ATV
- (DRV)
- LPV
- RAL
- RTV
- DTG
- TAF

Project update

	FORMULATION	RECOMMENDATION	PROGRESS	LEADER
ABC/3TC/ LPV/r	30mg/15mg/40mg/ 10mg granules	1st line in <3 y	DNDI/Cipla working on it.	DNDI
ABC/3TC/ EFV	150mg/75mg/150mg dispersible tablets	1st line in 3 to 10 y	Aurobindo, Hetero and Mylan were selected after EOI and are developing it.	MPP
RAL	50mg scored dispersible tablet (25mg or 50mg chewable also possible)	1st and 2nd line for <3 y	Hetero and Lupin have been licensed by the MPP and are working on it.	MPP
DRV/r	120/20 mg tablet	2nd line after failure to LPV/r and 3rd line	Working with Janssen, a plan has been developed to file modelling and PK data to support weight band dosing. Discussions on-going with manufacturers regarding formulation development plans.	CHAI
DTG-based formulations CHAI	Singles and FDC planned	1st and 2nd line	Clinical studies on-going by ViiV. Generics starting work on paediatric DTG. CHAI is implementing a collaboration with ViiV for development of a single DTG pediatric product and will work towards the FDC based on clinical data.	CHAI

Main bottlenecks



Regulatory: lack of clinical evidence

- Most formulations do not exist as originators, which complicates regulatory approval:
  - No bioequivalence reference (e.g. ABC/3TC/LPV/r)
  - Requirement of CT in India
- Original development plan by originator may not respond to current needs (e.g. DRV/r)
- Several companies working on slightly different formulations (e.g. RAL)
- Approval required time

Next steps

- Concentrate in resolving transversal issues affecting all projects;
  - Work with PAWG to provide technical input
  - Regulatory issues: common approach to address approval in India
  - Licensing management
  - Engage with generic companies to keep priority level
  - Focus on in-country registration
- Adapt PHTI activities and strategies to the GAP-f

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