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PROJECTING THE IMPACT OF GENERIC HIV DRUGS ON 90-90-90

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MEDICINES PATENT POOL

CONTENTS

1. Impact in terms of treatment affordability
2. Impact in making new treatments available faster
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INNOVATION IN HIV TREATMENT

- HIV treatment has witnessed innovation on a major scale
- Over 30 new antiretrovirals (ARVs) developed for the treatment of HIV since 1983
- Several “fixed dose combinations” developed that contain 3 or 4 ARVs in one single pill
- New medicines under development, including new mechanisms of action, new delivery systems, long acting formulations, implants, monoclonal antibodies, etc.

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IMPACT IN TERMS OF TREATMENT AFFORDABILITY

FUNDING TO PROCURE ARVS

Today:

- 21.7 million people on treatment worldwide of which at least **19 million people** in low and middle-income countries (based on UNAIDS data)
- At approximately **USD 85** per patient per year for 1st line (WHO GPRM; Global Fund) *
- Spending on ARVs in LMICs is estimated at approximately **USD 2 billion**

* Some countries procure at higher prices and 2nd and 3rd line ARVS are more expensive

FUNDING TO PROCURE TREATMENT

Without generic manufacturers (hypothetical):

- **Scenario 1**: at US$ 10,439 per patient per year*
  (lowest originator price in year 2000):
  we would need **US$ 198 billion** to procure medicines for the same number of people in LMICs

- **Scenario 2**: at US$ 613 per patient per year*
  (lowest originator price in 2017):
  we would need **US$ 11.6 billion** to procure medicines for the same number of people in LMICs
  or…
  if we only have USD 2 billion we would only be able to procure ARVs for approximately **3.3 million people** in LMICs

* MSF, Untangling the Web (2010) and MSF, HIV & Opportunistic Infection Treatment: Spotlight On Access Gaps (2017)

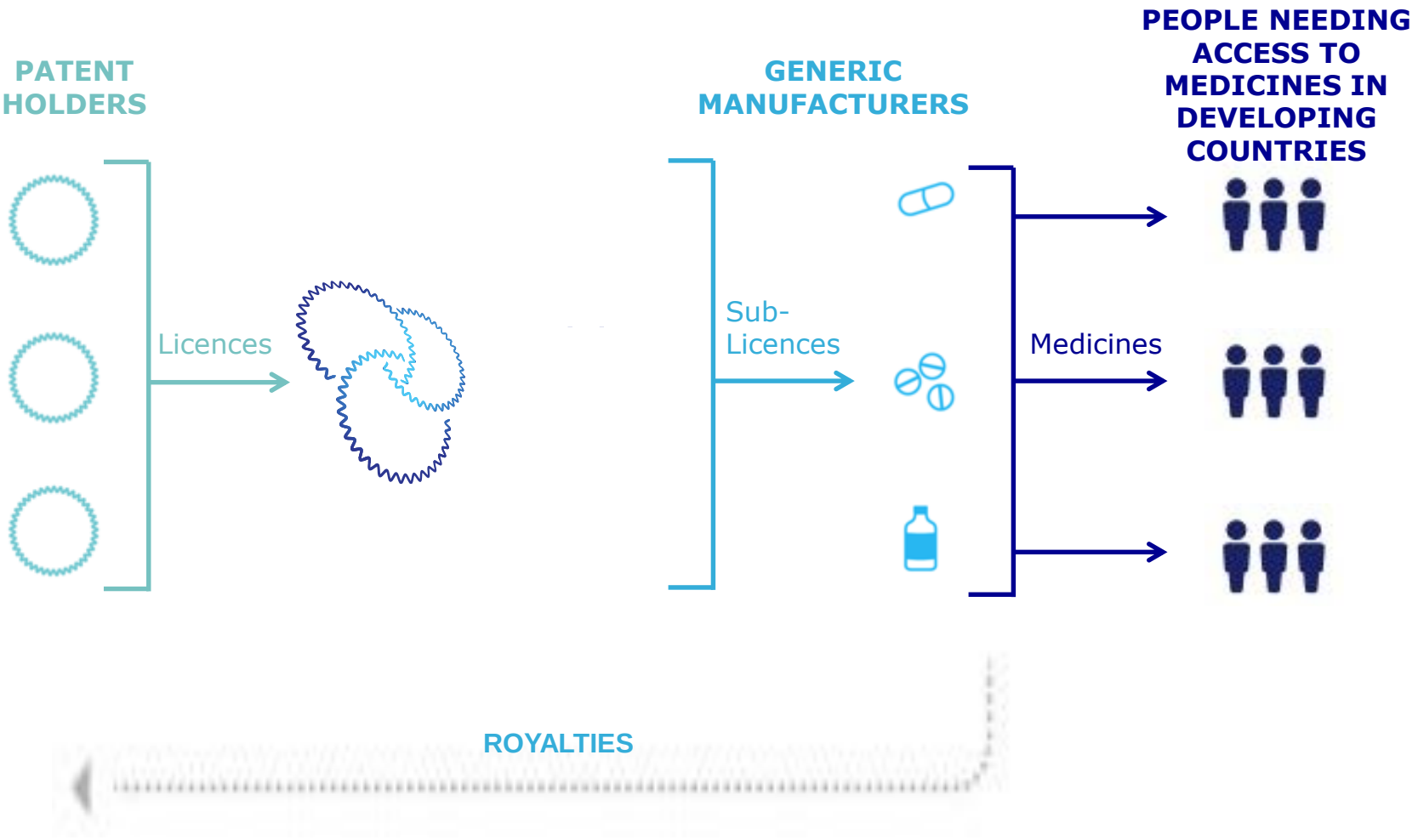
ACCESS ORIENTED LICENSING TO ENABLE GENERIC COMPETITION

- **Many factors contributed to large price reductions for ARVs through generic competition** enabling treatment scale up (donor funding, strong activism, development of national programs, political will, patent laws, generic manufacturers' ability to make quality-assured treatments, etc.)

- One key mechanism has been **access oriented licensing** which has increasingly become the norm in HIV

- Access-oriented licences are **agreements with the patent holders** that allow multiple manufacturers to make **generic versions of patented medicines** and supply large number of LMICs.

THE MEDICINES PATENT POOL: A PUBLIC HEALTH ORGANIZATION ENGAGED IN ACCESS ORIENTED LICENSING



The MPP is funded by Unitaid Innovation in Global Health

MPP LICENCES GEOGRAPHICAL COVERAGE (BASED ON WORLD BANK CLASSIFICATIONS)

Product(s) Licensed	LIC	LMIC	UMIC	HIC	Undefined	Total
Abacavir (paed.)	31	53	31	5	1	**121 +**
Atazanavir	31	52	32	3	3	**122 +**
Bictegravir	30	48	25	9	4	**116**
Cobicistat	30	48	25	9	4	**116**
Daclatasvir	31	46	30	2	3	**112 +**
Dolutegravir (paed.)	31	53	31	5	1	**121 +**
Dolutegravir	31	53	6	2	0	**92 +**
Elvitegravir	30	42	17	8	3	**100**
Lopinavir/Ritonavir (paed.)	31	50	19	2	0	**102**
Lopinavir/Ritonavir (Africa)	26	17	10	2	2	**57 +**
Raltegravir (paed.)	31	50	9	2	0	**92**
Ravidasvir	1	9	9	-	-	**19 #**
Sutezolid (global)	31	53	56	78	0	**218**
TDF	30	48	25	9	4	**116**
TAF	30	48	25	9	4	**116**

+ Additional countries may be able to procure generics

Complements DNDi licence for a total of over 130 countries

PARTNERSHIPS WITH INNOVATORS

abbvie

- Lopinavir
- Ritonavir

(seperate licences- adults and paediatrics)

Bristol-Myers Squibb

- Atazanavir
- Daclatasvir (HCV)

Boehringer Ingelheim

- Nevirapine (non-assert)

University of Liverpool

- Solid dispersion nanotechnology for HIV

GILEAD

- Bictegravir
- Cobicistat
- Elvitegravir
- Emtricitabine
- Tenofovir Alafenamide
- Tenofovir Disoproxil

janssen

- Darunavir (peadiatric non-assert)

MSD *Be well*

- Raltegravir (peadiatric)

Roche

- Valganciclovir (pricing agreement)

ViiV Healthcare

- Abacavir (paediatric)
- Dolutegravir (peadiatric)
- Dolutegravir (adults)

NIH

- Darunavir related

Johns Hopkins University

- Sutezolid (TB)

PHARCO Pharmaceuticals

- Ravidasvir (HCV)

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GENERIC PARTNERS

IMPACT ON 90-90-90

More affordable treatments contribute to the second 90, enabling more people to access treatment with available resources

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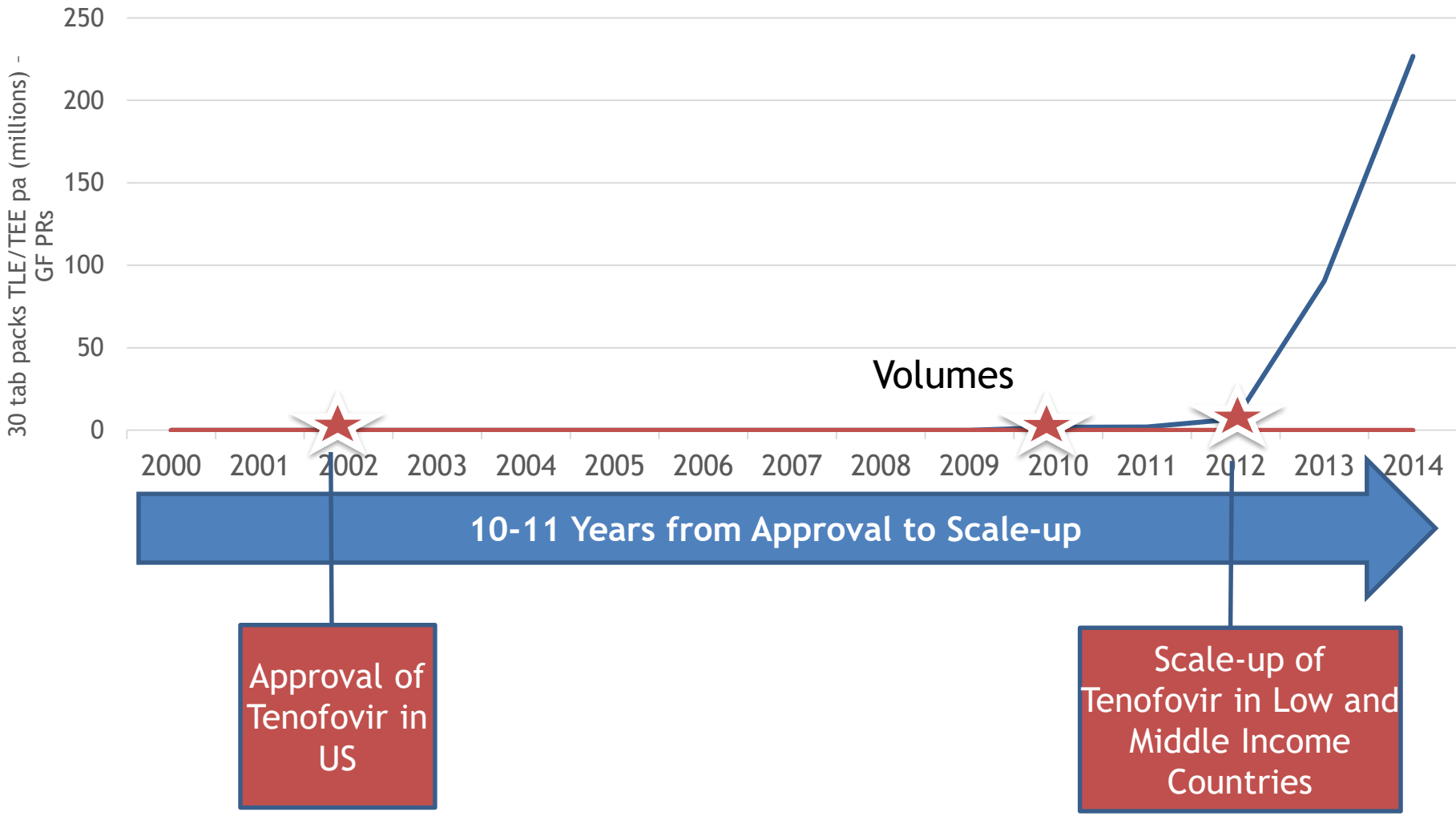
IMPACT IN MAKING NEW TREATMENTS ACCESSIBLE FASTER IN LMICS

IN THE PAST LONG DELAYS FOR UPTAKE OF NEW MEDICINES IN LOW AND MIDDLE INCOME COUNTRIES

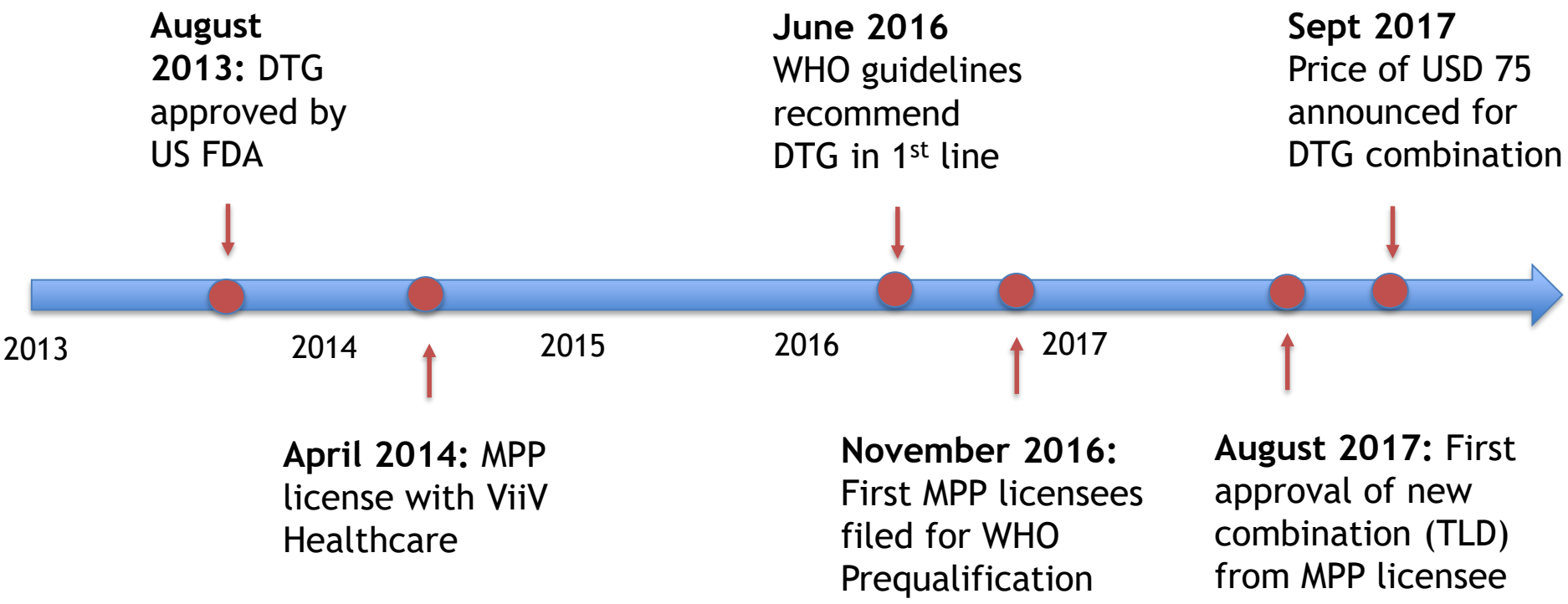
The Case of Tenofovir (TDF)



Source: GF PPM/PQR data. 2014 for part year;

THE CASE OF DOLUTEGRAVIR (DTG)

4 years from originator approval to availability from multiple suppliers in a new fixed dose combination ("TLD") at affordable prices



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IMPACT IN MAKING NEEDED NEW FORMULATIONS

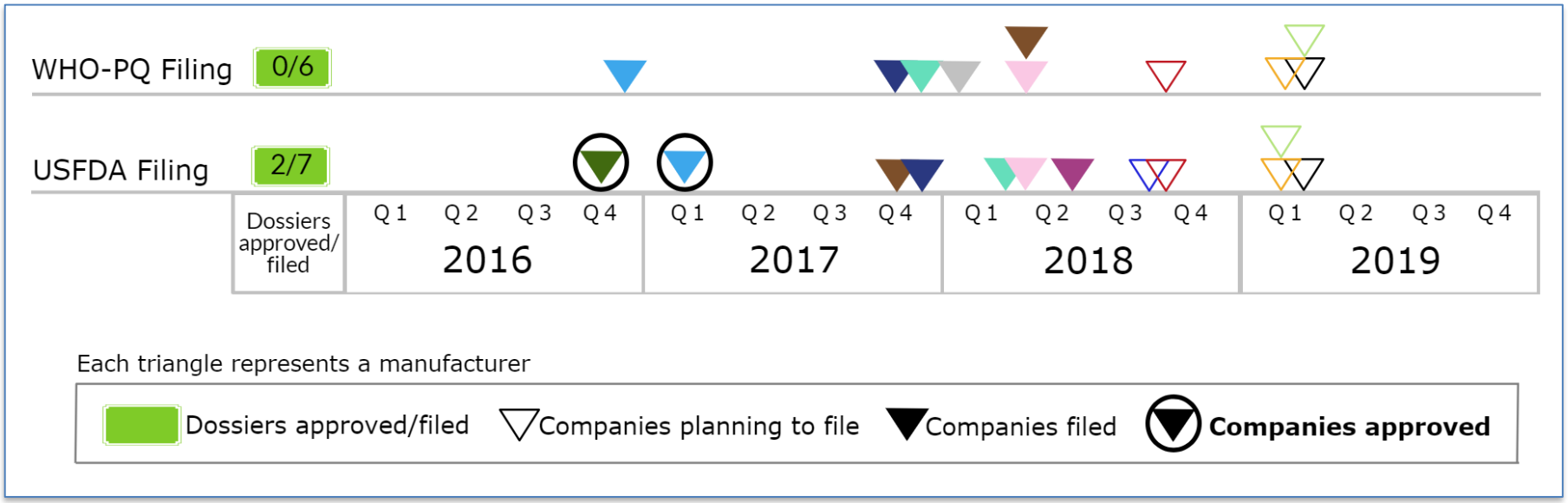
Case of Tenofovir/lamivudine/dolutegravir (TLD)

- Dolutegravir has higher barrier to resistance than current first line with efavirenz (SPRING trial)
- It is better tolerated, with fewer treatment discontinuations
- TDF: enables treatment for hepatitis B in co-infected people and no need for HLA-B*5701 screening
- Potential for lower price than efavirenz combination

Caution regarding potential safety signal for women with HIV at time of conception (issue to be further discussed at IAS)

http://www.who.int/medicines/publications/drugalerts/Statement_on_DTG_18May_2018final.pdf

TDF/3TC/DTG
(TENOFOVIR DISOPROXIL/LAMIVUDINE/DOLUTEGRAVIR)



- 13 MPP licensees are currently developing TDF/3TC/DTG, of which:
  - 6 have filed with WHO-PQ
  - 7 have filed with USFDA; of which **two** have received approvals
- **4 companies** have received approval by the WHO/Global Fund Expert Review Panel
- In all, **2 generic versions of TLD** are already in the market and an **additional 4** are expected to be launched soon

TDF/3TC/DTG: Country-wise Filing Status

Approved (6) (19.4% PLHIV in LMICs)
Botswana
Côte d'Ivoire
India
Kenya
Malawi
Uzbekistan

Filed (25) (69.2% PLHIV in LMICs)		
Benin	Ghana	South Africa
Burkina Faso	Madagascar	Tanzania
Burundi	Mali	Uganda
Cameroon	Mozambique	Ukraine
Congo	Namibia	Vietnam
DR Congo	Niger	Zambia
El Salvador	Nigeria	Zimbabwe
Ethiopia	Rwanda	
Gabon	Senegal	

Generic TLD has been filed in 31 countries, of which approval is received from 6

Another 25 filings are planned for 2018

Paediatric formulations

LPV/r *(sprinkles in sachet or minitabs in capsule)*	• Three companies working on this product: 1. **One company** has received USFDA approval 2. Another has filed with WHO-PQ and USFDA in Q1-18 3. The third plans to file with USFDA and WHO-PQ in Q3-19
LPV/r/ABC/3TC *(sprinkles in sachet or minitabs in capsule)*	• Three companies working on this product: 1. One plans to file with USFDA and WHO-PQ in Dec-18 2. Another plans to file with USFDA and WHO-PQ in 2019 3. Another developing, filing status and plans unknown
ABC/3TC/EFV	• Three companies working on the product • Filing plans in 2019
ABC/3TC/DTG	• Multiple companies interested in development, awaiting WHO recommendation on dosage

IMPACT ON 90-90-90

Faster access to new optimized ARVs and development of needed adult and paediatric formulations contributes to the third 90, through access to optimized formulations that are better tolerated, lower treatment discontinuations, higher resistance barrier

The MPP's HIV, TB and hepatitis C activities are fully funded by:

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THANK YOU

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