Access to 2nd Line and 3rd Line Treatment in Middle-Income Countries

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make medicines affordable
END UNFAIR MONOPOLIES

ITPC
INTERNATIONAL TREATMENT PREPAREDNESS COALITION

Introduction

- In 2016: 17 Millions of PLHIV are receiving ART
- Access to routine viral load testing is scaling up

→Increased need for 2nd and 3rd line regimens

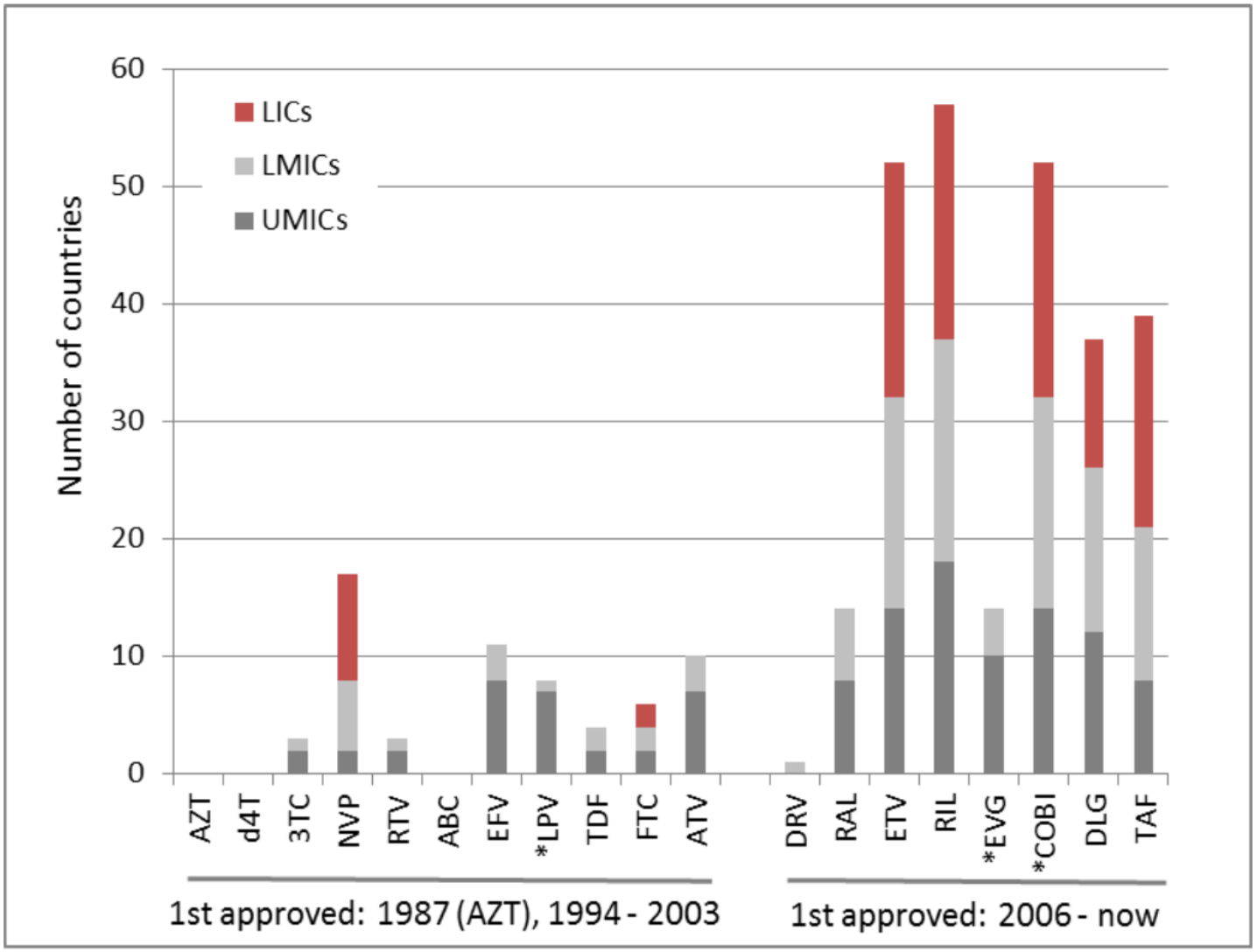
- Middle-Income Countries (MICs) initiated treatment programs earlier (late 90s)
- First generation of ARVs: more toxic, several side effects, adherence problems, low genetic barrier

→ Needs greater in MICs

Middle-Income Countries

- 70% of PLHIV will be living in MIC by 2020 (UNAIDS)
- Treatment coverage is lower in several MICs than in Sub-Saharan Africa
- MICs are loosing support of Global Donors (GFATM, PEPFAR)
- MICs are excluded from Pharma access programs and voluntary licenses
- Filing patents has significally increased in MICs since 2006

Patent filing in Middle Income Countries



Based on information available for 80 countries in MPP database (Dec. 2013)

Quality vs Affordability?

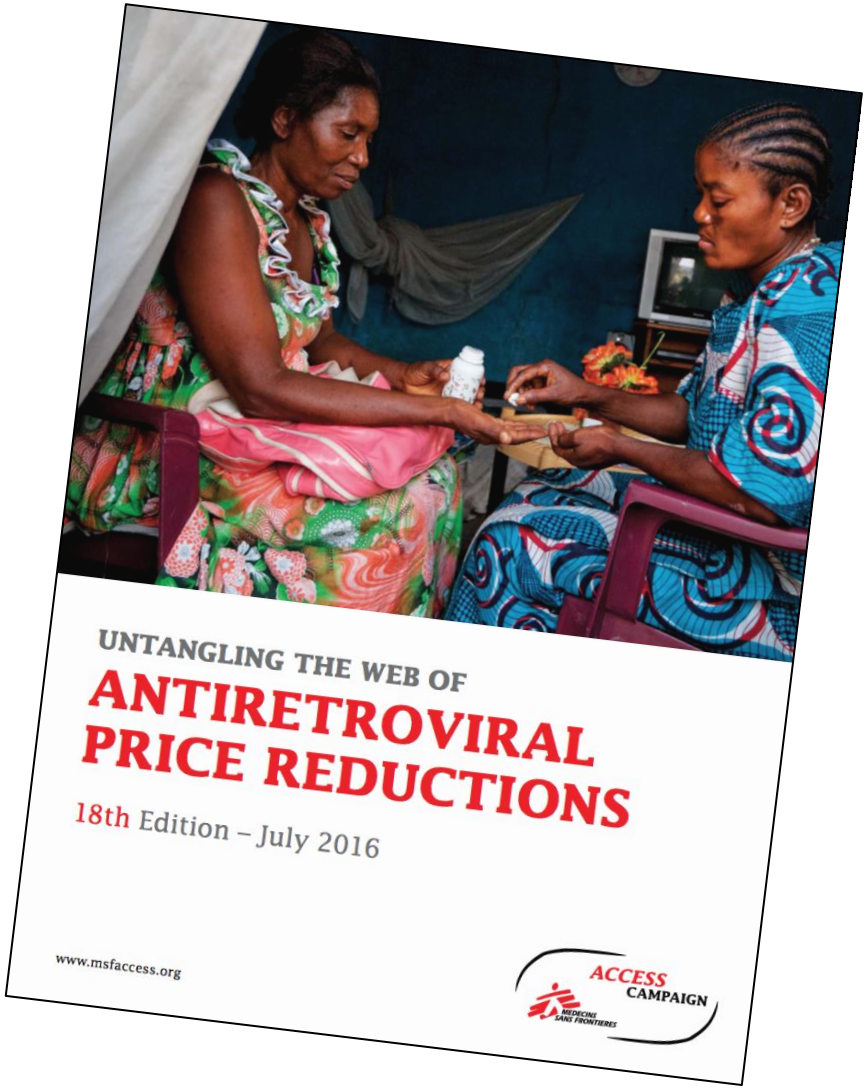
- WHO (and national guidelines) set preferred ARV regimens
- Affordability is a KEY determinant of guideline's implementation:
  - Fixed dose combination of TDF-based regimens is largely used in subsaharan Africa vs AZT-based regimens in several MIC
  - ATV/r is largely used in LICs vs LPV/r
  - Kenya, Botswana, South Africa are in process to use DTG as first line

→ Quality GAP between low and middle income countries!

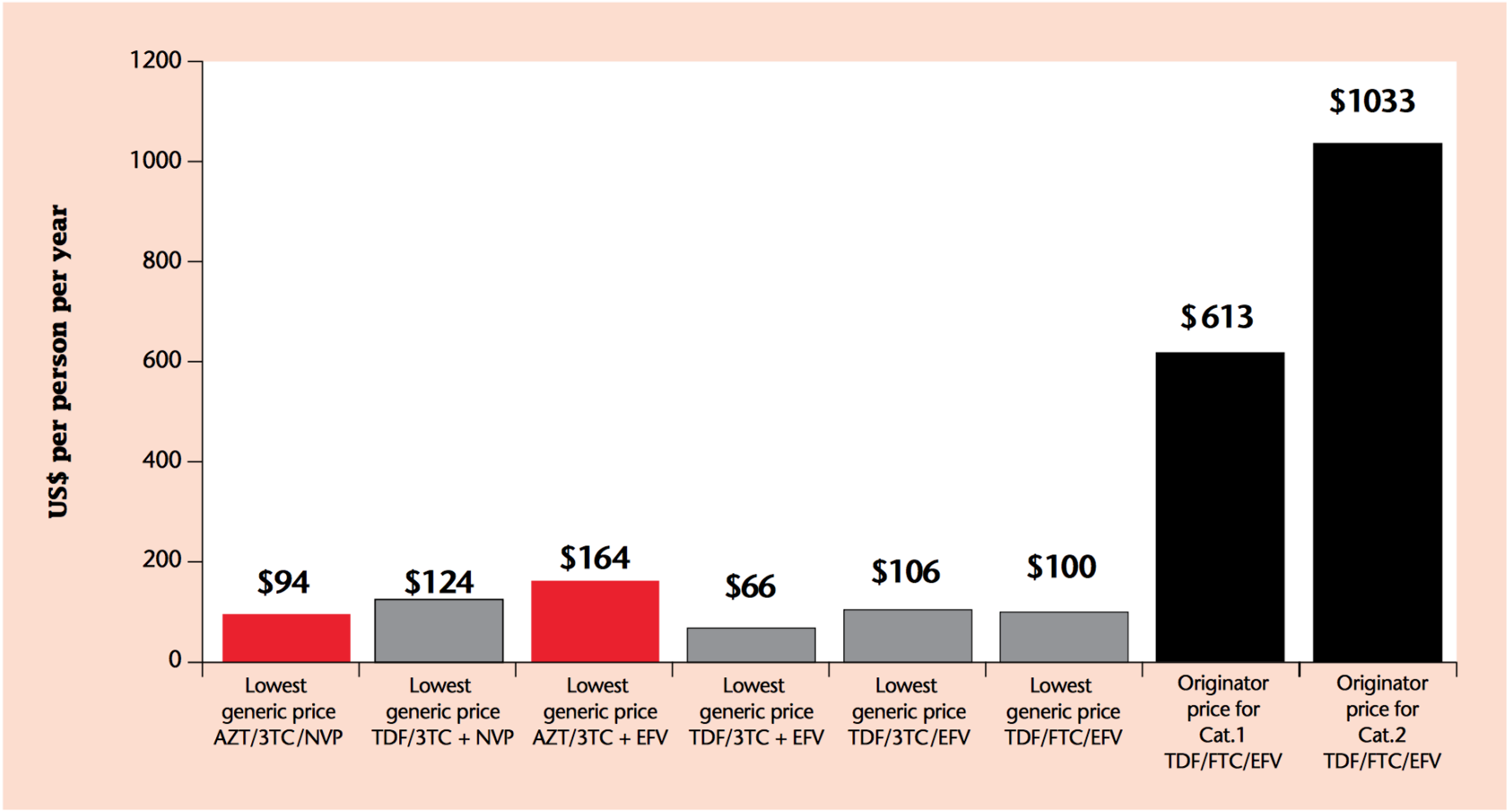
WHO 2015 Guidelines and Treatment Optimization

- Improving 1st line regimens:
  - Inclusion of DTG (more potent, high genetic barrier, low side effects)
- Better 2nd line regimens:
  - Fixed dose combination of DRV/r
  - RAL+LPV/r

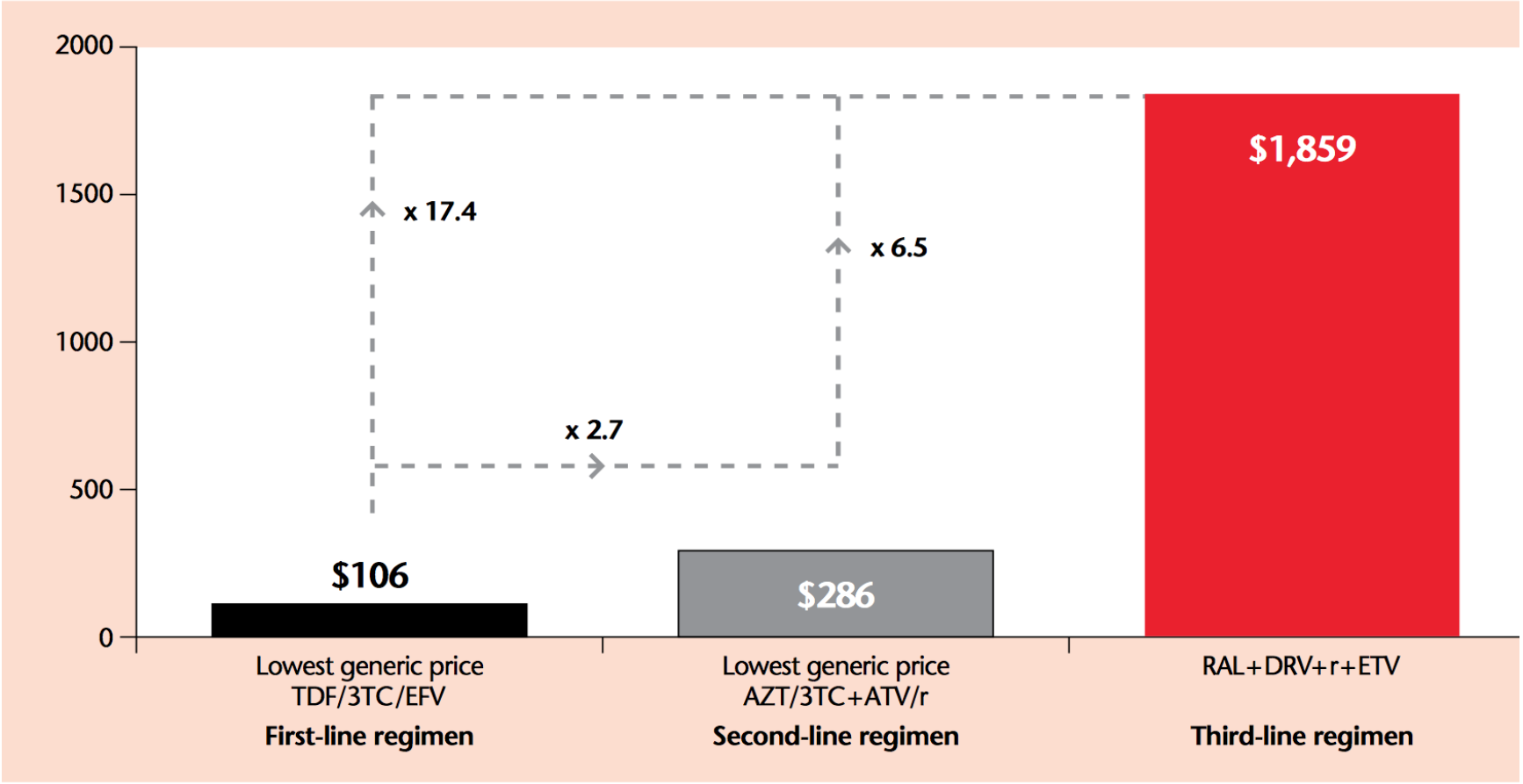
Where are we in Pricing?



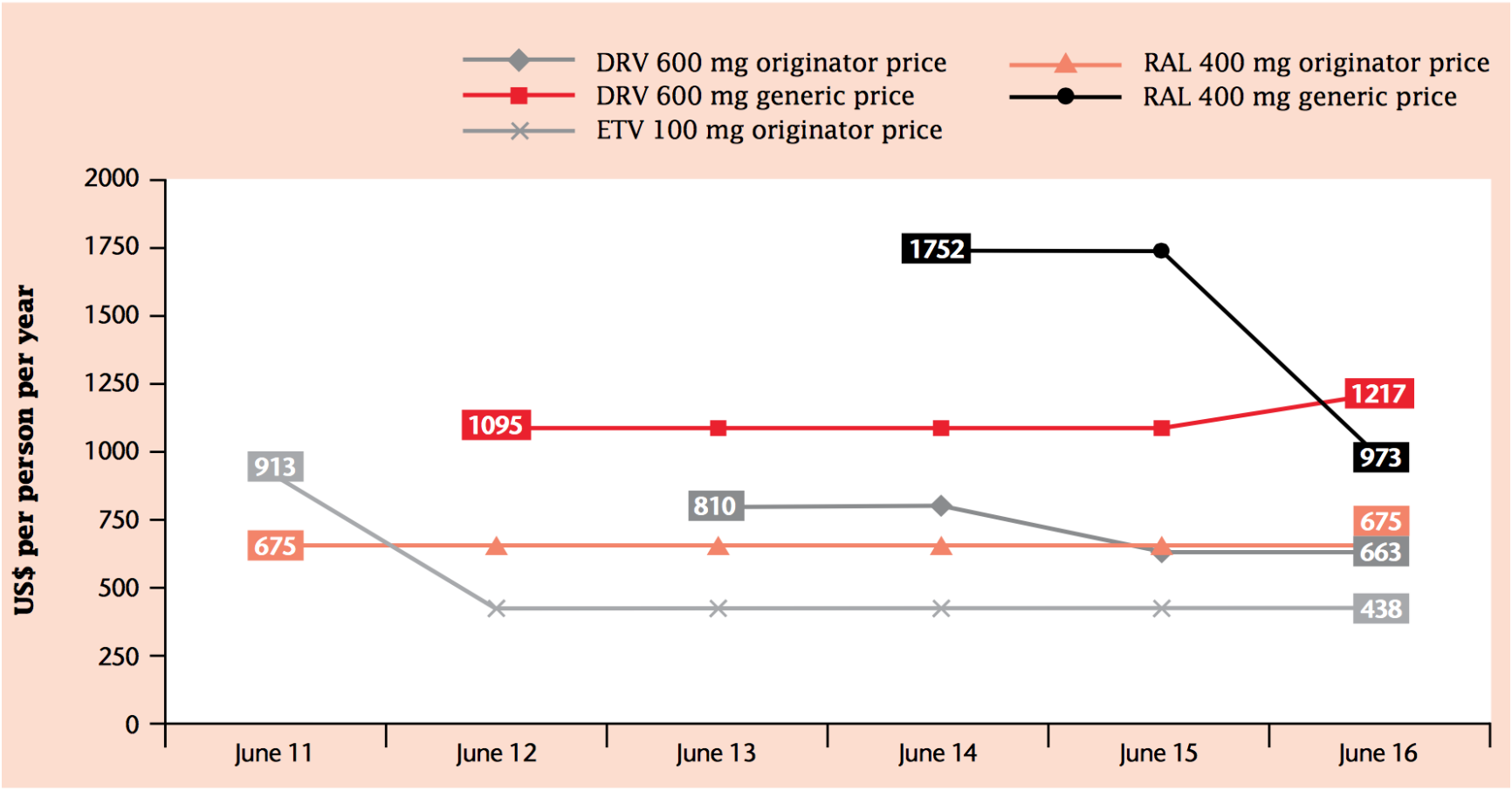
Prices of first line regimens today (MSF)



Prices comparisons of 1st line, 2nd line and possible 3rd line regimens (MSF)



Prices for 3rd line ARVs (MSF)



Examples of prices in 4 MICs

	Argentina	Brazil	Thailand	Ukraine	Lowest price (MSF+CHAI)
ATV	2.366	715	1.749	NA	207
DRV	2.985	2.102	466	5.520	438
DTG	3.573	NA	NA	NA	44
ETR	7.509	2.613	3.451	NA	438
LPV/r	1.408	613	531	740	108
RAL	5.102	3.635	4.582	4.258	675

So what are the options?

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- Voluntary/Collaborative approaches:
  - Tiered pricing
  - Voluntary licences
- Legal/Human Rights based approaches (TRIPS Flexibilities)
  - Strict patentability criteria, public health approach to patent examination
  - Compulsory Licences
  - Parallel importations

Limits of Voluntary Approaches

- Voluntary
- Negotiated prices remain high: do not guarantee lowest prices possible
- Exclusion of MICs and countries with high disease burden (Russia, China…) from licence territory
- Introduce new/additional barriers even in countries where there are no patents
- Little leverage/implication of governments

TRIPS Flexibilities

- Government owned and controlled
- Compulsory licences have been used successfully between 2000-10 by countries leading to massive price reductions
- Patent oppositions for key ARVs (TDF and LPV/r) in India enabled
- Pressure from developed countries (US, EU…)
- Leadership and role of Civil Society+++

Make Medicines Affordable Campaign

- Consortium led by ITPC: I-MAK, ABIA, Fondation GEP, AIDS Access Foundation, All Ukrainian Network of PLHIV
- 3 Years, Funded by UNITAID ($6M)
- 4 MIC countries: Argentina, Brazil, Thailand, Ukraine
- Objective: Remove IP barriers to generics market entry for 10 key ARVs
- Impact expected: $150M annual savings across 10 target ARVs (Additional 130.000 PLHIV treated by savings)

Key Interventions

- Advocacy for Law reform
- Support public health approaches to patent examination
- Prevent adoption of TRIPS+ provisions in national laws (FTAs)
- File patent oppositions on selected ARVs
- Use of compulsory licences on selected ARVs

DTG case in Morocco

- DTG is anti-integrase inhibitor (ViiV)
- Recommended by WHO alternative 1st line regimen, 2nd and 3rd line
- US price: 14.000$ pppy
- Protected by patent in Morocco until 2026
- Morocco excluded from the Medicines Patent Pool licence
- National AIDS program interested to replace Raltegravir(3rd line) and/or 1st line *if affordable*

Civil society campaigns on DTG

- Protest letters to ViiV and MPP on Morocco's exclusion from licence
- Mobilisation of HIV, Health and Human Rights coalition
- Work with media
- Development of an « Access » strategy based on compulsory licence → meetings with MoH and HIV physicians


DTG
FOR ALL
AFRICA
NOW


WILL I SURVIVE?
DTG FOR ALL AFRICA NOW


WILL I SURVIVE?


WILL I SURVIVE?
ITPC


Tivicay
dolutegravir
TIVICAY REGISTERED IN 83 COUNTRIES WO
WILL I
SURViiVE?


WILL I SURViiVE?


RIATT-ESA works to ensure that global, regional and national policy & programmes work for children nd families affected HIV.
WILL I SURViVE?


WILL I SURVIVE?
WILL I SURVIVE?
WILL I SURVIVE?
WILL I SURVIVE?
WILL I SURVIVE?
STIGMA FREE SERVICES FOR WOMEN LIVING WITH HIV
STIGMA FOR ALL AFRICA NOW
STIGMA FOR ALL AFRICA NOW

Compulsory licence campaign

- Several meetings with ViiV in UK and Morocco
- ViiV offers discount: 1.700$ pppy
- World AIDS Day: CS Coalition calls on MoH to suspend patent on DTG by Government use licence supported by HIV physicians
- Several advocacy meetings with MoH and ViiV
- MoH refuses ViiV's discount and explores CL

→ April 2016: ViiV announces non enforcement of patent in Morocco and MPPs extend licence territory to Morocco and 3 other LMICs

Conclusion

- Price and affordability is a key determinant of access to Medicines
- Patents and other intellectual property barriers are a real challenge in MICs
- Quality and sustainability of treatment access programs is at stake
- Voluntary mechanisms don’t work for middle income countries
- Only the use of TRIPS flexibilities can make medicines affordable and secure access

The New Targets:

$90 $90 $90

There could be standard prices for HIV, Hepatitis B and Hepatitis C in low/middle income countries. Worldwide:

$90 per year to treat HIV

$90 per year to treat Hepatitis B

$90 for a 12 week course of treatment to cure Hepatitis C

make

medicines

affordable

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