

IP and regulatory barriers in LMICs HIV and co-infection medicines

APACC, 2018
Hongkong, June 2018



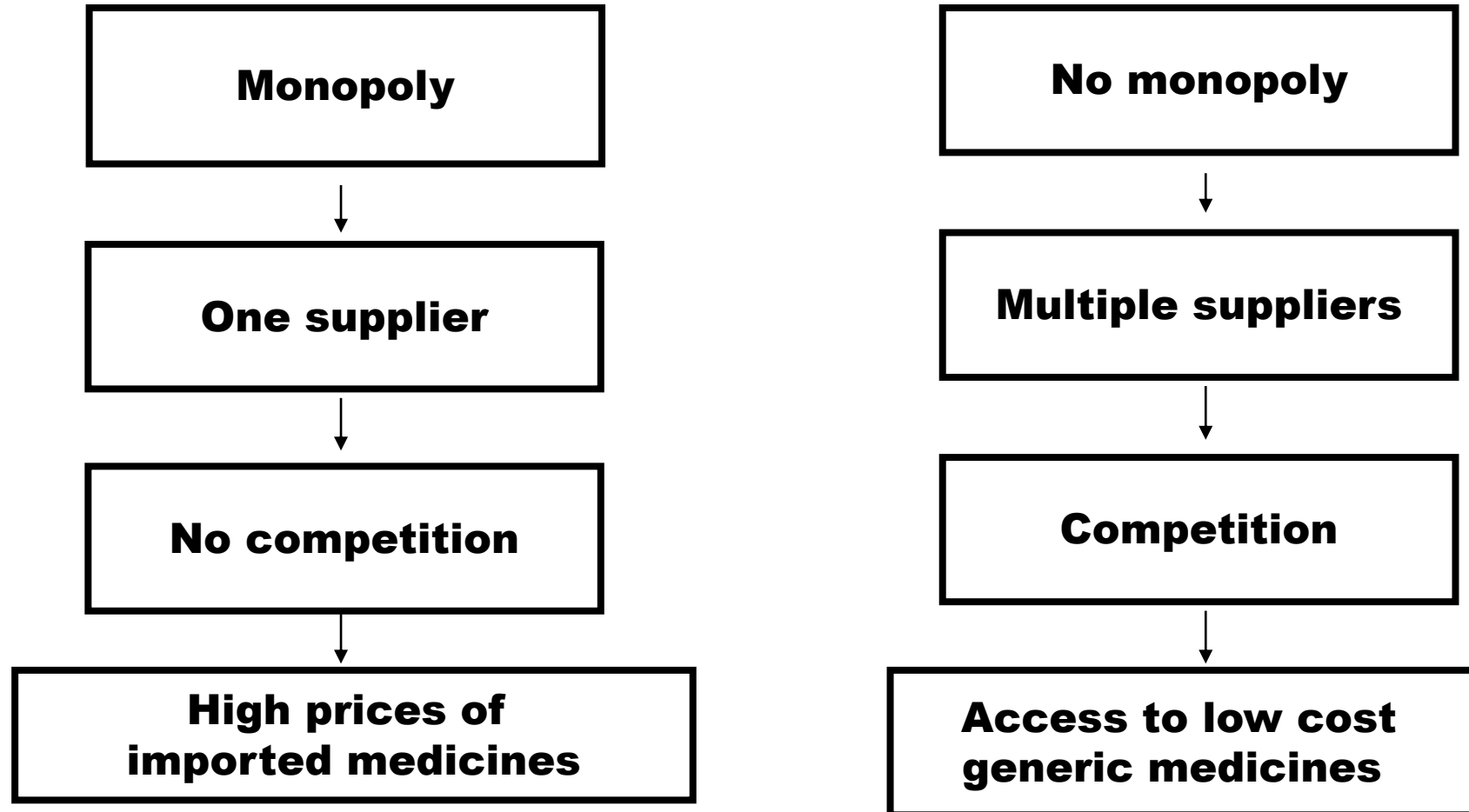


MEDICINES
SHOULDN'T BE
A LUXURY

www.msfacecess.org

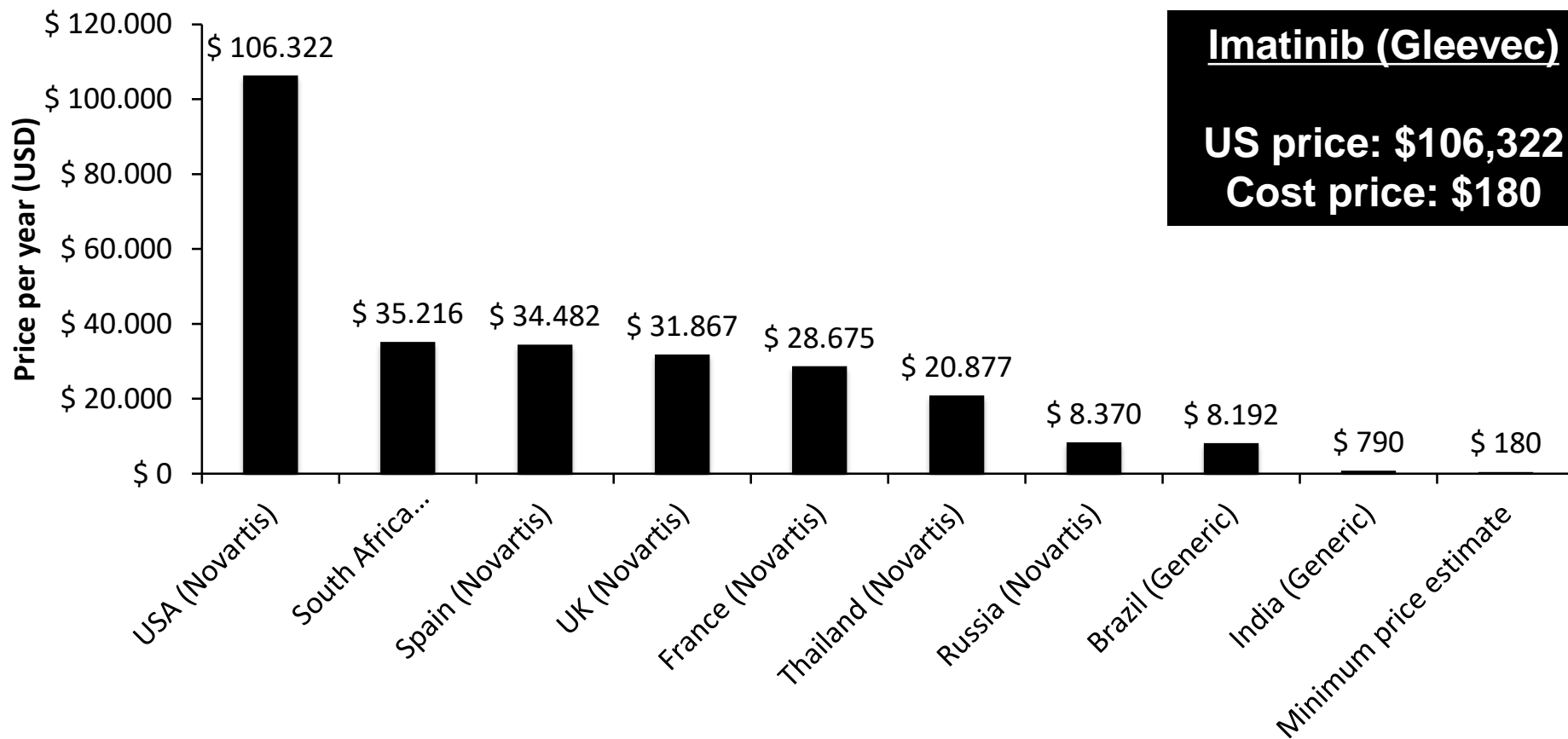


Monopolies linked to Prices



1000\$ a pill to 3\$ a pill for HCV

Lowest available price for Imatinib (400mg) in selected countries



Brief history



- Late nineties, 40 mill people with HIV
- 8000 people a day died of AIDS in the developing world
- Effective antiretroviral medicines (ARVs) available @ \$15,000 pppy
- No fixed dose combinations (FDCs) available from originators
- 2001 Indian generic companies offered the same ARVs (FDC) for \$350 pppy

National and international legal and political conflicts over patents were common ->

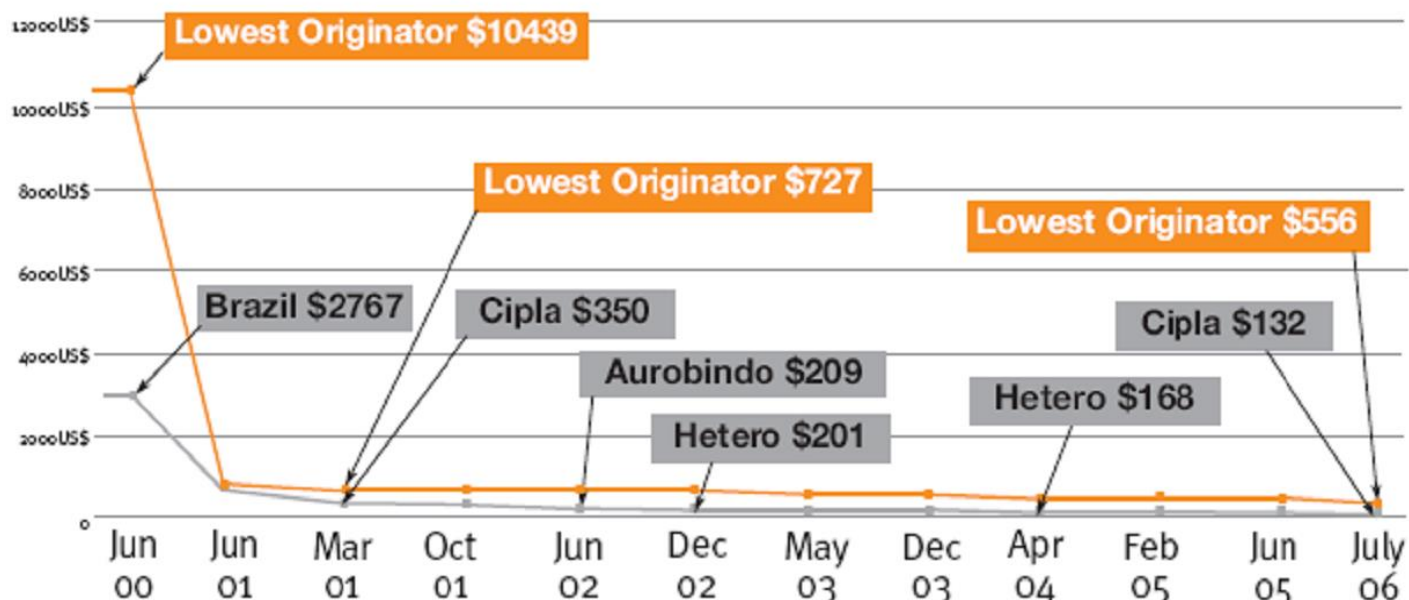
IN THE HIGH COURT OF SOUTH AFRICA (TRANSVAAL
PROVINCIAL DIVISION) Case number: 4183/98



Generic competition needed to drive prices down: the example of AIDS medicines

Graph 1: Sample of ARV triple-combination: stavudine (d₄T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.

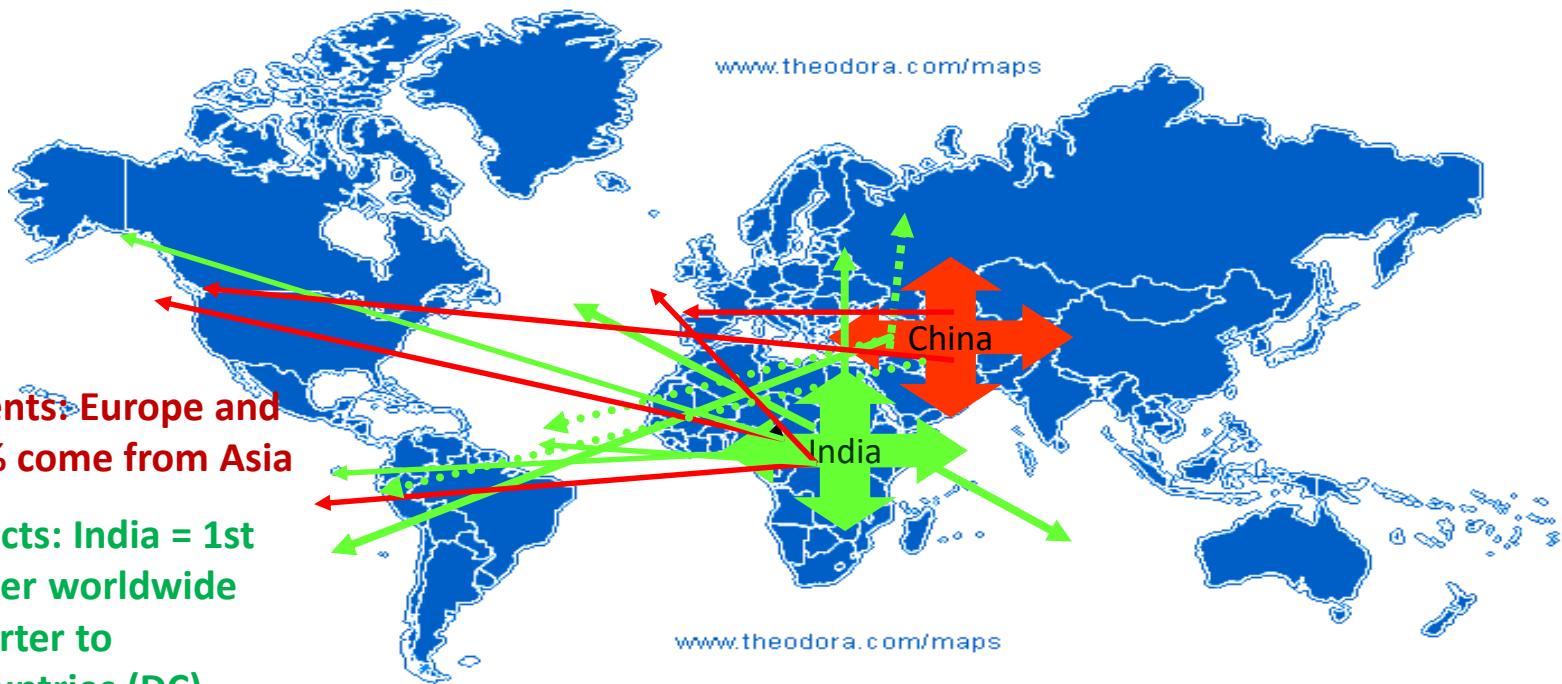
The Effects of Generic Competition June 2000-June 2006



Generic competition has shown to be the most effective means of lowering drug prices.

Production of medicines

TODAY



- **Active Ingredients:** Europe and USA: 80 to 90% come from Asia
- **Finished Products:** India = 1st generic producer worldwide and main exporter to Developing Countries (DC).
- 56% of Indian exports are made in D.C.
- More than 50% of worldwide prescriptions are generics. Can be 80% - 90% in some developing countries

Active Ingredients
Finished Products

Globalisation of Patent Rules

- 1995 WTO Trade related aspects of intellectual property rights agreement (TRIPS)
- “minimum” standards of protection of intellectual property rights
- 20 year patents on pharmaceutical products
- No differentiation between lifesaving medicines and trivial goods
- 2005 Indian amended its patents act to be compliant with TRIPS and starts to grant product patents (transition period ends)
- Civil society challenges patent claims relating to fixed dose combinations and other trivial evergreening claims, leading to ARVs (1st & 2nd line) being generically produced.

Classification of countries and impact on access

Under WTO:

Developed, developing and least developing countries (self selection)

Under World Bank:

The World Bank assigns the world's economies into four income groups — high, upper-middle, lower-middle, and low.

WTO classification linked to patent system. The World Bank classification often used by pharmaceutical corporations for tiered pricing, inclusion and exclusion in voluntary licenses to Medicines Patent Pool or generic companies.

Lopinavir/ritonavir and ritonavir patents in MICs

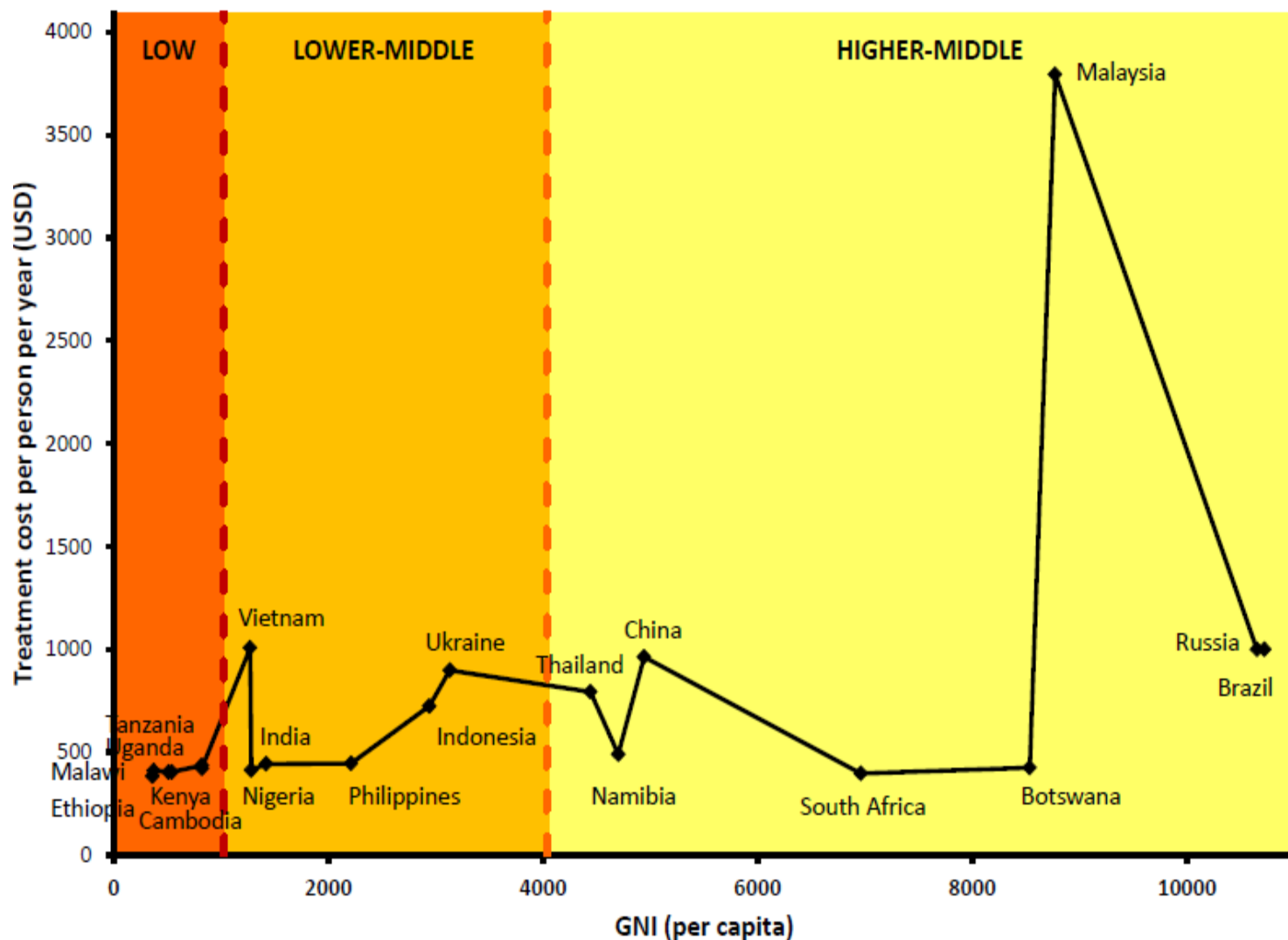
Patented extensively by Abbott in MICs

Indian civil society defeats all patent claims – evergreening

Generics become available

MICs struggle to access not just LPV/r but ritonavir patents on tablet formulation undermine access to ATZ/r, paediatric formulations

Median Annual Treatment Cost of LPV/r 400/100mg BID



Sofosbuvir and other DAAs

- Context: Provide an effective cure (>90%) for HCV and vulnerable communities PLHIVs and drug users need urgent access
- Sofosbuvir launched at \$1000 a pill in the US (USD 84,000 for 12 weeks)
- Patent barriers tackled in Egypt and India - Generics developed and launched by Egyptian and Indian generic companies (WHO PQ involved in quality assurance). MSF secures \$120 for a 12 week course of SOF/DAC
- Gilead's and BMS licenses exclude key MICs (Thailand, Malaysia, China, Ukraine)
- 2017 Malaysia issues a compulsory license to obtain access to generics for sofosbuvir (400,000 people living with hepatitis C) goal to reduce prices to USD 300 for 12 week regimen
- Not just a MIC problem - Treatment rationing in Hongkong
- 8000 USD for three months of sofosbuvir in China (major barrier)

Drug Resistant TB

M/XDR TB – 2 year treatment with drugs with major side effects with less than < 50% efficacy. DR-TB affects PLHIVs disproportionately

New drugs like bedaquiline offer new hope

New TB drugs – bedaquiline and delamanid difficult to access

Access under compassionate use (CU) is - patient by patient – importation limited to countries where J&J offers a CU programme

US and Japanese pharmaceutical corporations sole supplier – have been slow to register in high burden developing countries. How are FDAs approaching registration?

SA replaces injectable with oral medicine bedaquiline (June 2018)

J&J pricing: 900 USD for LICs, 3000 for MICs and 30,000 for HICs

Patented extensively in the region including MICs



Any Questions?