

# Treatment Expansion in Access & Emerging Markets

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Gilead Sciences



**GILEAD**

Advancing Therapeutics.  
Improving Lives.

# Gilead Sciences

## **Mission: Discover, develop and deliver innovative medicines in areas of unmet medical need**

- 7,000 employees in 28 countries on 5 continents
- 16 marketed medicines (US) and more than 250 ongoing and planned clinical studies

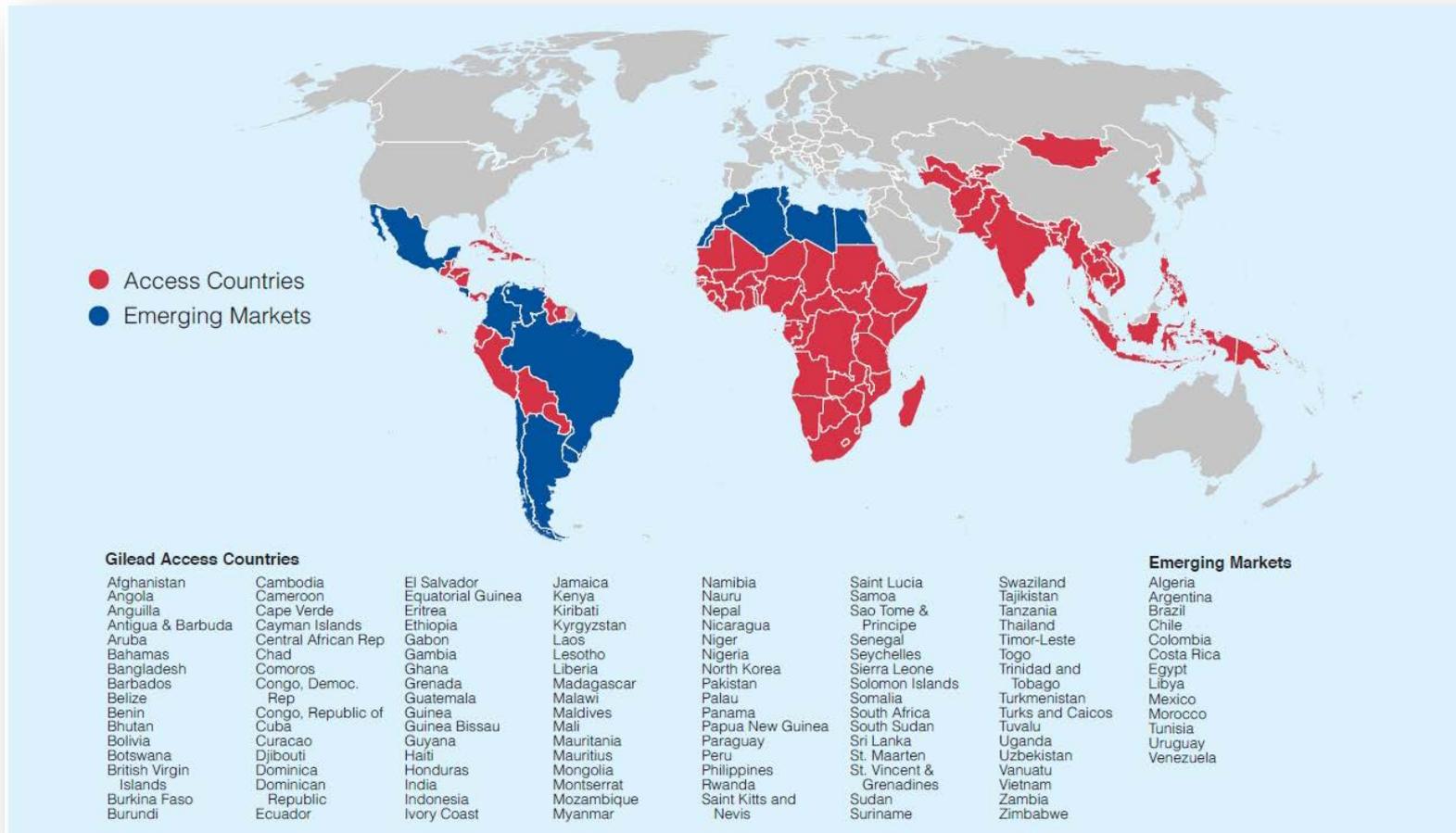
## **Focus on patient needs**

- All people should have access to our medicines, regardless of where they live or their economic status
- Gilead also supports medical education and local health system improvement



# Access Operations & Emerging Markets Geography

Gilead medicines reach patients in **125 countries** supplied by **20 regional business partners**



# Gilead Access Medicines

Gilead's developing world programs enable access to **eight medicines and generic versions of their chemical compounds**



Viread® (TDF)	tenofovir disoproxil fumarate 300 mg
Truvada® (TDF/FTC)	emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg
Complera® (RVP/TDF/FTC)	emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg
Tybost®	cobicistat 150mg
Vitekta®	elvitegravir 150mg
Stribild® (EVG/COBI/TDF/FTC)	elvitegravir 150 mg/cobicistat 150 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg
Sovaldi®	sofosbuvir 400 mg
AmBisome® <sup>1</sup>	amphotericin b liposome for injection 50 mg/vial

<sup>1</sup> AmBisome is not available in generic form. Gilead provides AmBisome to public sector agencies at no-profit prices and donates the medicine to WHO for use in high-burden countries.

# Innovative Use of Intellectual Property



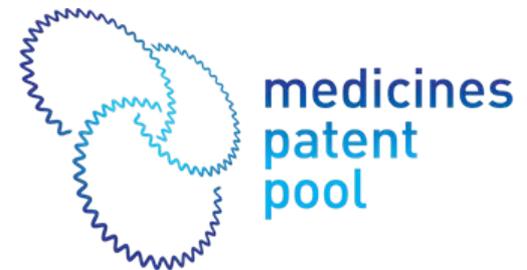
## Generic Licensing

- Full technology transfer
- Partners seek WHO/FDA certification
- Small royalty to ensure sustainability
- **HCV: 7 Indian licensees**
- **HIV and HBV: 17 Indian and African licensees**
- Collaboration with HIV licensees to improve FTC manufacturing process and waive royalties

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## Medicines Patent Pool

- UN-supported initiative to enhance drug access through sharing of patents
- Gilead first innovator company to join (2011)



# Critical Support Activities: Product Registration

**Regional business partners help register medicines with national regulatory authorities**, ensuring that documents conform to national requirements and are processed efficiently

Gilead Medicine	Truvada	Complera	Stribild	Viread for HIV	Viread for HBV	Sovaldi
Developing World Registrations	109	21	7	109	65	1

  
**REPUBLIQUE DU NIGER**  
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**MINISTRE DE LA SANTE PUBLIQUE**  
 DIRECTION GENERALE DE LA SANTE PUBLIQUE  
 DIRECTION DE LA PHARMACIE DES LABORATOIRES ET  
 DE LA MEDECINE TRADITIONNELLE  
 BP. 623 NIAMEY  
 Tél. (227) 20 72 26 65  
 (227)20 72 24 50

Décision n° **0033**/MSP/DGSP/DPHU  
 Du **1 MAR 2014**  
 (Régularisation)

**LE MINISTRE DE LA SANTE PUBLIQUE**

Vu La Constitution du 25 Novembre 2010;  
 Vu L'Ordonnance N° 97-002 du 10 Janvier 1997, portant législation pharmaceutique ;  
 Vu Le Décret N°97-301/PRN/MSP du 06 Août 1997, fixant les modalités d'application de l'Ordonnance N° 97-002 du 10 Janvier 1997, portant

  
**Ministry of Health Jamaica**  
**Pharmaceutical Product Licence**  
 The pharmaceutical product listed hereunder has been registered and is licensed to be imported and sold in Jamaica in accordance with the *Food & Drugs Regulations (1975) # 65*.

**Product(s):** Stribild Tablets  
 (Each tablet contains 150mg elvitegravir, 150mg cobicistat, 200mg emtricitabine, 300mg tenofovir disoproxil fumarate equivalent to 245mg tenofovir disoproxil

**Conditions of Licensing:** List 4 Prescription Only Drug

**Licence Number:** 6E 426  
2014 April 11

**Product-licence Holder:** Gilead Sciences In., USA



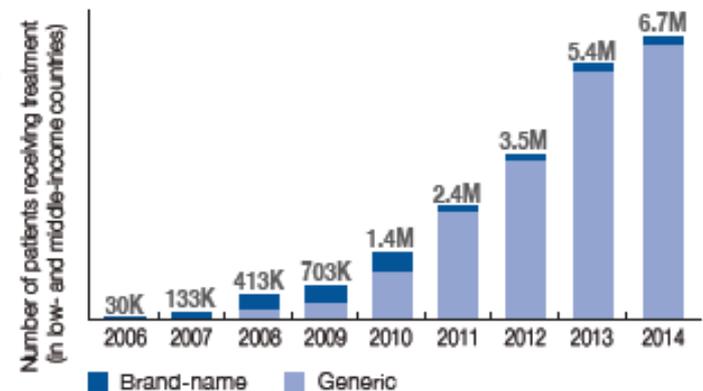
# Increasing Patient Reach

**More than 50%** of patients on antiretroviral therapy in the developing world are receiving Gilead medicines

Generic drug manufacturers account for 99% of Gilead HIV medicines prescribed in developing countries



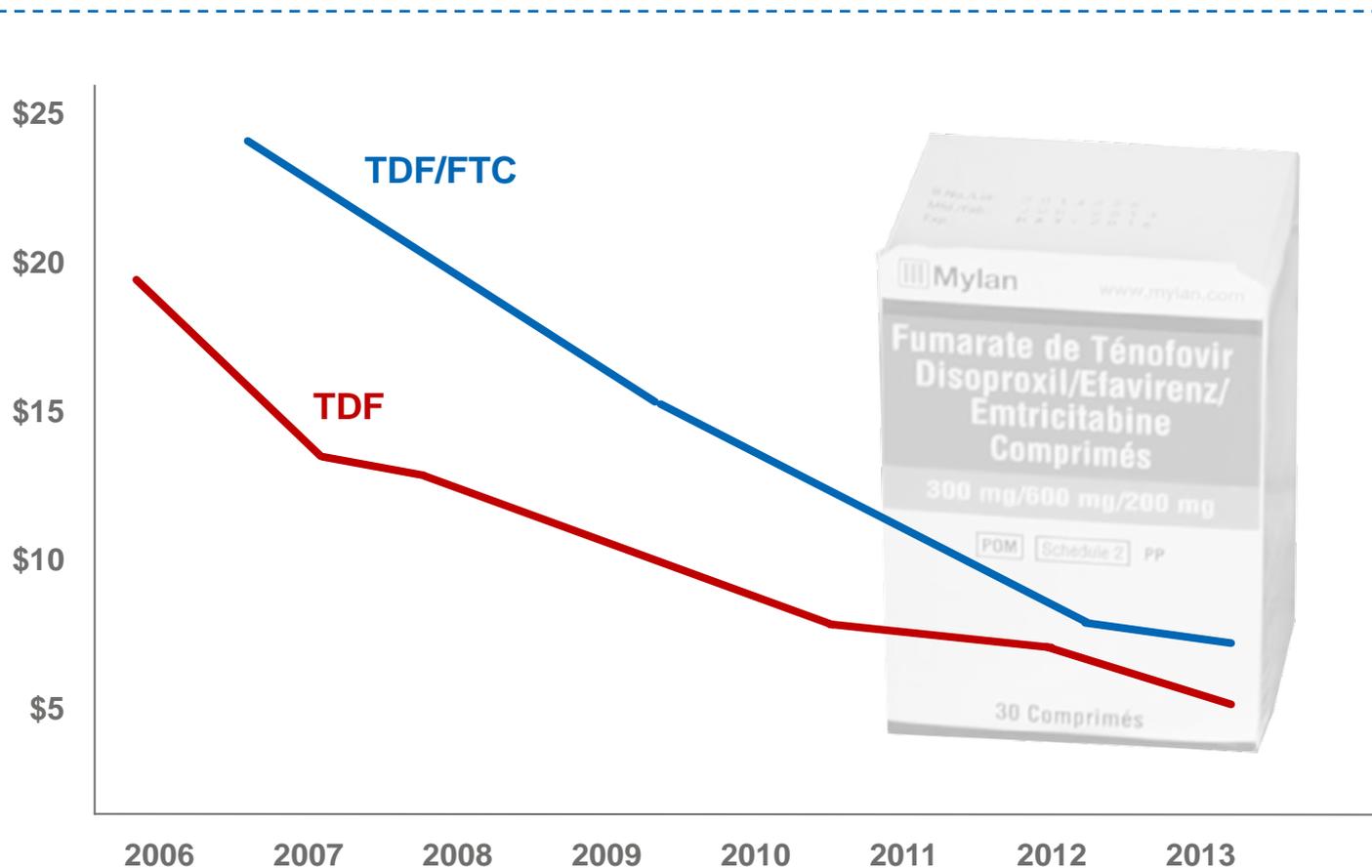
Access to Gilead HIV Medicines





# Increased Competition Lowers Drug Prices

**17 generic partners** are licensed to manufacture and sell Gilead HIV therapies; market competition has helped **reduce the cost of TDF by 80% since 2006**



# Viral Hepatitis Treatment Expansion



## Hepatitis B

- Viread for hepatitis B is available in same 125+ countries and at same prices as for HIV
- Viread for HBV is now registered in over 60 countries and has been filed for approval or is pending submission in more than 50 additional countries



## Hepatitis C

- WHO HCV treatment guidelines recommend treatment with Sovaldi for genotypes 1-4
- Three tiered pricing bands for branded Sovaldi
- Generic licensing
- NGO / Gov't partnerships

# Chronic Hepatitis C



Gilead's strategy is to invest in **long-term partnerships with governments and NGOs** to implement public health plans, and engage regulatory and funding agencies to support national treatment strategies

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**Tiered pricing of Sovaldi** in low-, lower-middle and upper-middle income countries

**Licensed generic sofosbuvir** to produce lost cost versions for distribution in developing countries

**Over 20 regional business partnerships** to manage supply chains and distribute branded Sovaldi in developing countries

**Registration** of Sovaldi, focusing initially on the highest-burden countries

**Medical education** to train health care providers in hepatitis C diagnosis and care



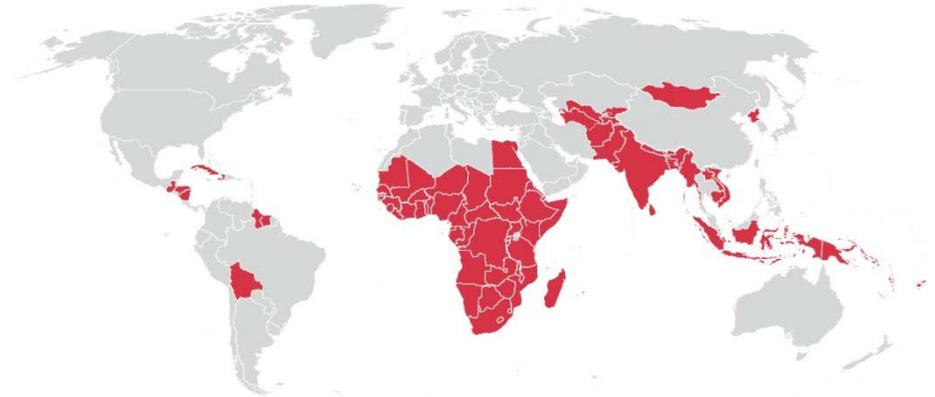
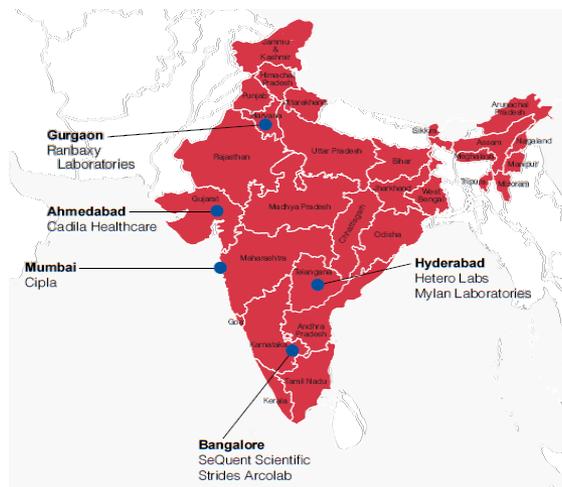
## 15<sup>th</sup> September 2014: Gilead Sciences signed non-exclusive license agreements with seven generic pharmaceutical manufacturers to expand access to hepatitis C medicines in developing countries

- Companies granted rights to manufacture **sofosbuvir** and the investigational single tablet regimen of **ledipasvir/sofosbuvir\*** for distribution in 91 developing countries
  - The countries account for more than 100 million people living with hepatitis C globally – 54% of the total global infected population
  - Companies receive a complete technology transfer of the Gilead manufacturing process to enable them to scale up production as quickly as possible
  - Licensees required to manufacture to local Indian DCGI quality standards
  - Licensees set their own prices for the product they produce, paying a royalty on sales to Gilead to support product registrations, medical education/training, safety monitoring and other business essential activities
  - Large-volume generic manufacturing and distribution is widely regarded as a key component in expanding access to medicines. These agreements are essential to advancing the goals of our humanitarian program in these countries.



# Indian Generic Licensees

- Cadila Healthcare Ltd
- Cipla Ltd
- Hetero Labs Ltd
- Mylan Laboratories Ltd
- Ranbaxy Laboratories Ltd
- Strides Arcolab Ltd
- Sequent Scientific Ltd



**More than 100 million people living with hepatitis C**

- 91 countries included
- 54% of the estimated HCV infected global population
- 75% of countries designated low-middle Income
- 90% of people living in low-middle income countries

# Breaking New Ground in Egypt



- HCV prevalence is higher in Egypt than in any other country in the world
- An estimated **7.2% of Egyptians are chronically infected with HCV**
- Egypt has been a high priority for Gilead's HCV treatment expansion efforts
- Gilead and Egypt's National Liver Committee signed agreement in March 2014
- Gilead will partner on medical education and training initiatives



# Tiered Pricing



- Three basic tiered pricing bands that serve as the starting point for negotiations with national governments
- Countries are categorized within the bands according to gross national income (GNI) per capita (a reflection of the average income of a country's citizens) and hepatitis C prevalence.
  - The tiers follow World Bank nomenclature of (i) Low-income; (ii) Lower-middle-income; (iii) Upper-middle-income
  - Gilead classifies more countries as low- and lower-middle-income than the World Bank does
  - As disease prevalence is considered, some countries classified as lower-middle-income by the World Bank are included in Gilead's lowest tier
- Final prices are determined on a country-by-country basis

# Recognition of Gilead's Access Efforts



## Access to Medicine Index

- **#1** ranking in product pricing
- **#1** ranking in use of patents to expand access



## Patents for Humanity

- Innovative use of IP recognized by U.S. Patent and Trademark Office's "Patents for Humanity" award

## Challenges for hepatitis rollout in access territories

- Compared to HIV access, access to medications for hepatitis B and C will require innovative strategies for country specific acquisition and distribution
  - Programs such as the Global Fund or PEPFAR are not yet in place for hepatitis B and C monoinfected patients
  - Rollout in HIV coinfecting patients may be easiest at first
  - Will require commitment on the part of local governments to purchase and distribute drugs, even at access pricing
  - Infrastructure for delivery is a challenge
  - Competing healthcare and economic priorities
  - Innovative financing strategies may be possible in selected countries