

# **Global Health, IP & TRIPS at 20**

*Twin Challenges of Innovation and  
Access: Leveraging IP to Achieve Both*

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Corporate and Medical Affairs

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**GILEAD**

Advancing Therapeutics.  
Improving Lives.

# Gilead's Commitment to Innovation and Access

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

- Active ingredient in Gilead's HIV medicines is the most widely prescribed molecule (TDF) for HIV therapy worldwide.
- New hepatitis C (HCV) regimens provide a simple, safe and highly effective cure; an all-oral regimen to treat all HCV patients (pan-genotypic) is in development.

## **Focus on patient needs**

- Guiding principle: All people should have access to our medicines, regardless of where they live or their economic status.
- As part of a comprehensive access approach, Gilead has entered into licensing agreements with generic pharmaceutical manufacturers to create a sustainable, market-based model for broadening access to HIV, hepatitis B (HBV) and HCV medicines in the developing world.
- Our partnership model for HIV now reaches **8 million patients** in developing countries.

# More Than a Decade of Progress

Gilead launches its  
**HIV Access Program**

Gilead becomes the **first HIV manufacturer** to sign a licensing agreement with the Medicines Patent Pool

Gilead's first **hepatitis C medicine becomes available in Egypt**, the highest-burden country in the world, less than a year after its U.S. approval

Gilead HIV medicines reach **8 million patients** in the developing world

2003

2006

2011

2012

2013

2014

2015

Gilead expands HIV Access Program through **licensing agreements with Indian generic manufacturers**

Gilead is **ranked #1 by the Access to Medicine Index** for patents/licensing and equitable pricing

Gilead **licenses its hepatitis C medicines** to India-based generic manufacturers

Gilead **expands its hepatitis C licensing agreements** to include more countries and products  
Gilead **makes its branded hepatitis C medicines available at their lowest prices** in all countries in its expanded generic-eligible territory

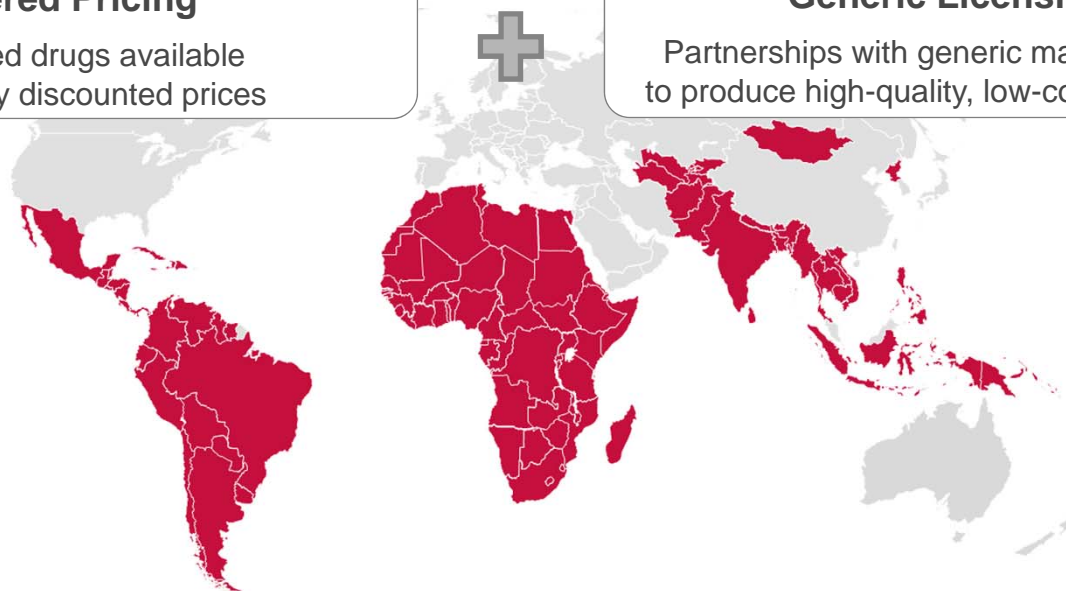
# Our Model of Treatment Expansion

## Tiered Pricing

Branded drugs available  
at deeply discounted prices

## Generic Licensing

Partnerships with generic manufacturers  
to produce high-quality, low-cost medicines



## Drug Registration

Working with network  
of business partners  
to submit regulatory  
dossiers on a country  
by country basis

## Relevant Data

Broad clinical trials across  
broad patient populations;  
local clinical trials where  
appropriate; key  
demonstration projects

## Partnerships & Health Systems Strengthening

Agreements with non-profit  
service providers and on the  
ground medical education and  
training

## Product Donations

Targeted donations enabling  
treatment initiation for key  
underserved populations

# HIV Treatment Access

Supporting the global movement for universal access

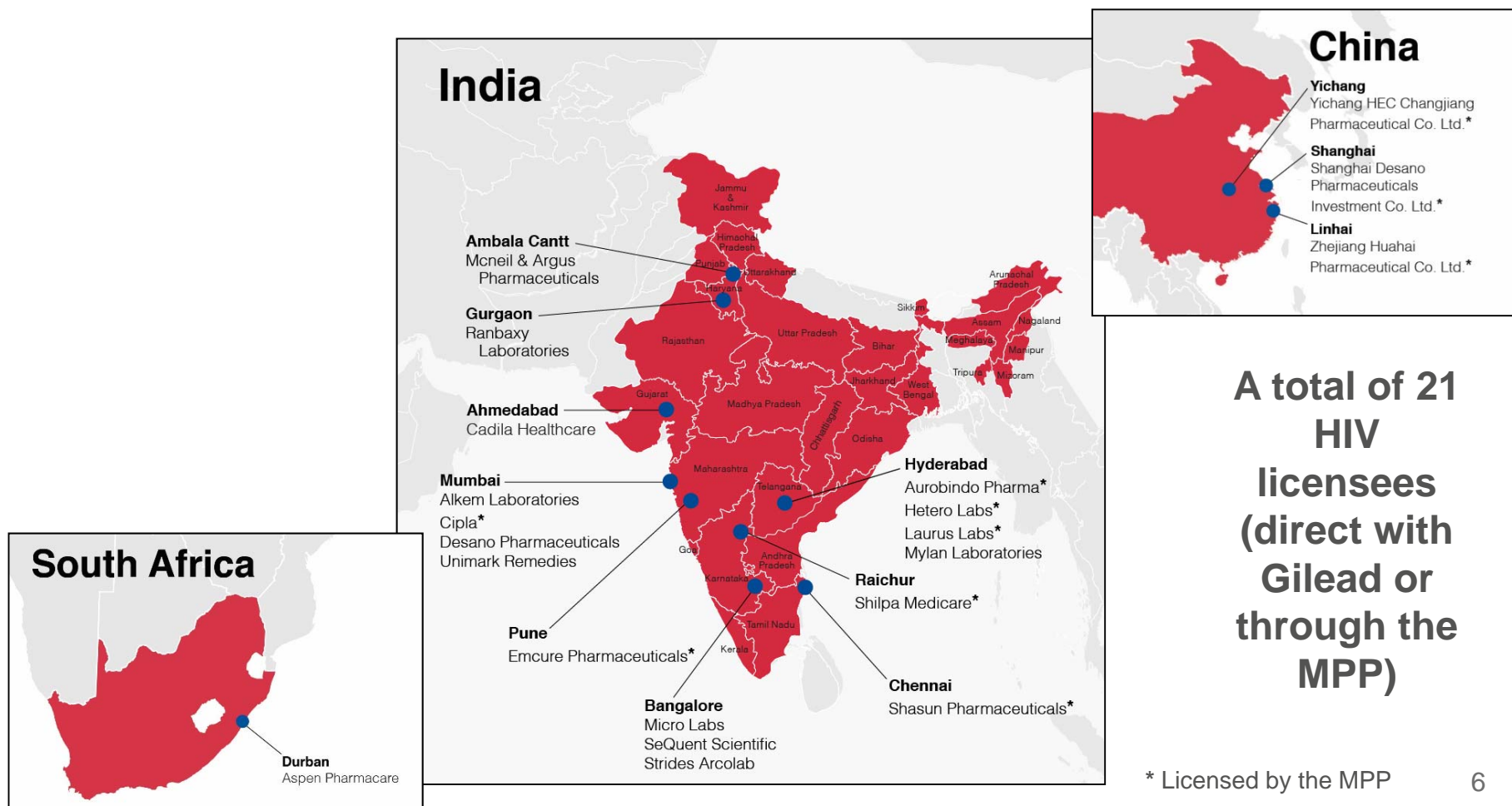
1996

2006

2015

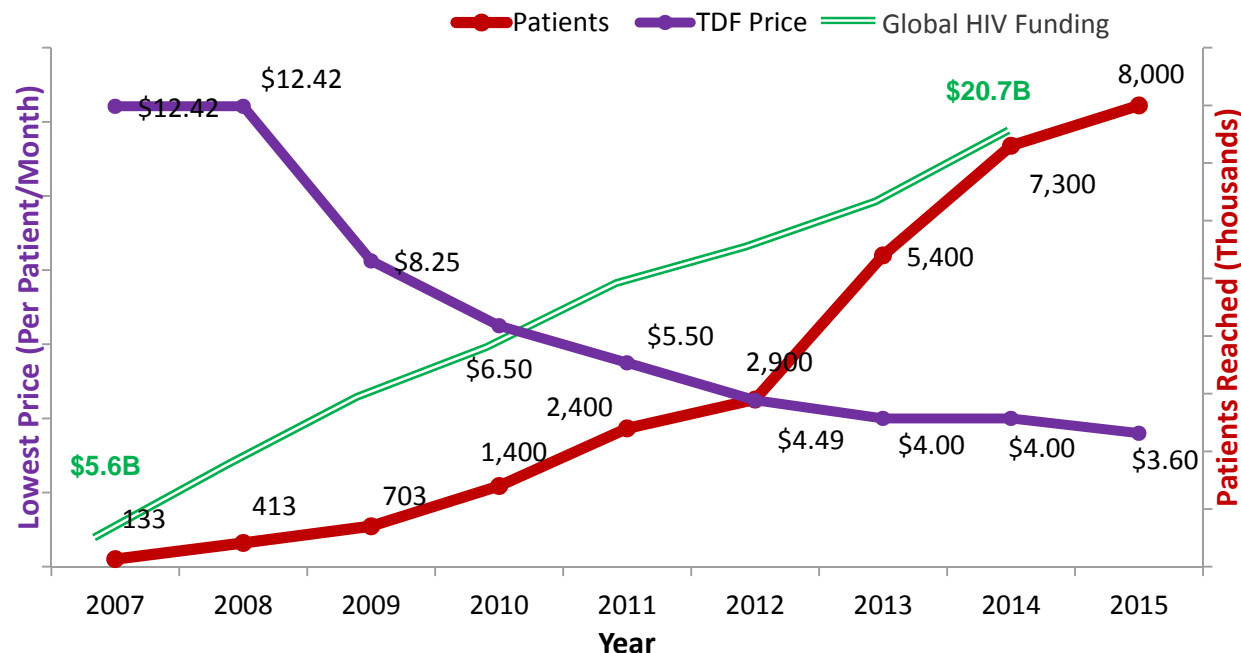


# HIV Generic Licensing Partners



## Generic Competition + Innovative Financing = ↓ Prices & ↑ Access

Driven by competition among licensed generic manufacturers and supported by global funding, the cost of Gilead HIV medicines has **fallen by 80%**. **More than half of HIV patients** on ARVs in the developing world are now receiving Gilead medicines.



# Accelerating Access to New HIV Treatments

- Even before new HIV treatments are approved, Gilead is working to expedite access to them.
- Tenofovir alafenamide (TAF) represents Gilead's latest treatment innovation.
  - High efficacy at a dose  $<1/10$  that of Viread® (TDF)
  - Improved kidney and bone safety parameters
- In July 2014, Gilead expanded its MPP agreement to increase access to TAF for HIV and hepatitis B, contingent on U.S. regulatory approval.
  - U.S. PDUFA date November 5, 2015
  - EU MAA submitted in December 2014
- MPP can sub-license TAF to generic drug companies in India and China, who may manufacture and distribute it in **112 developing countries**.



*"The MPP announcement reflects the importance of ensuring rapid access to new lower-dose HIV medicines for people living with HIV/AIDS worldwide and accelerating efforts to control the HIV/AIDS epidemic."*

**- Ambassador Deborah Birx**, U.S. Global AIDS Coordinator (July 24, 2014)



# Continued Discovery in HIV

## TAF Regulatory and Research Updates

<b>Q1 2015</b> Initiated Phase 2 study of <b>new integrase inhibitor (GS-9883)</b> with F/TAF	<b>Q2 2015</b> Submitted applications for <b>F/TAF</b> in the U.S. and EU	<b>Q3 2015</b> Submitted applications for <b>rilpivirine/F/TAF</b> in the U.S. and EU	<b>Q4 2015</b> Anticipated approval of <b>E/C/F/TAF</b> in the U.S. and EU
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## HIV Eradication Research Updates

<b>Q1 2015</b> Presented promising pre-clinical data on <b>GS-9620</b>	<b>Q2 2015</b> Initiated <b>Phase 1 study</b> to show proof-of-concept in humans		
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# Hepatitis C Treatment Access

Rapid scale-up for global impact

2011-2013

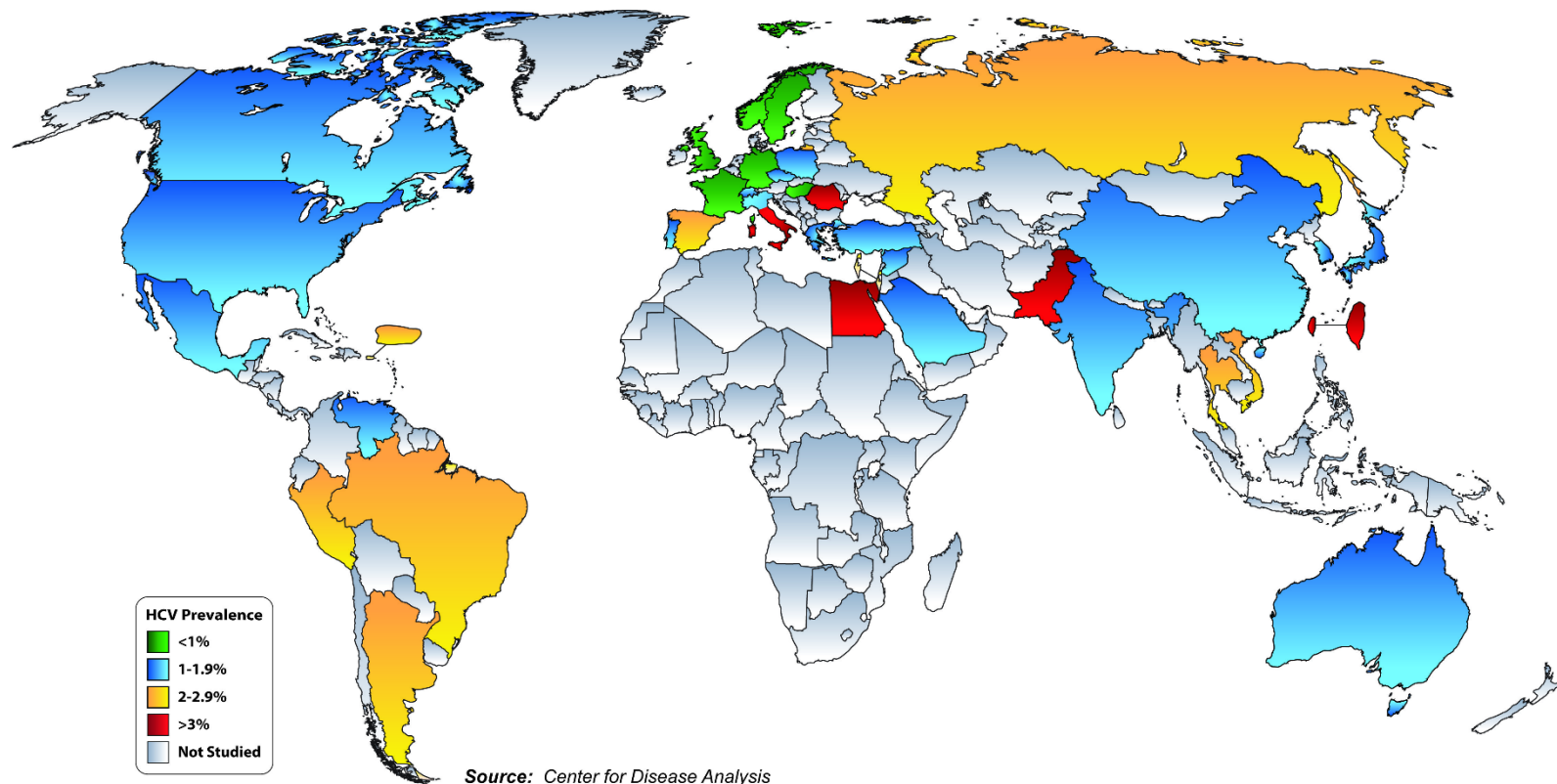


2014



# Global Prevalence of Hepatitis C

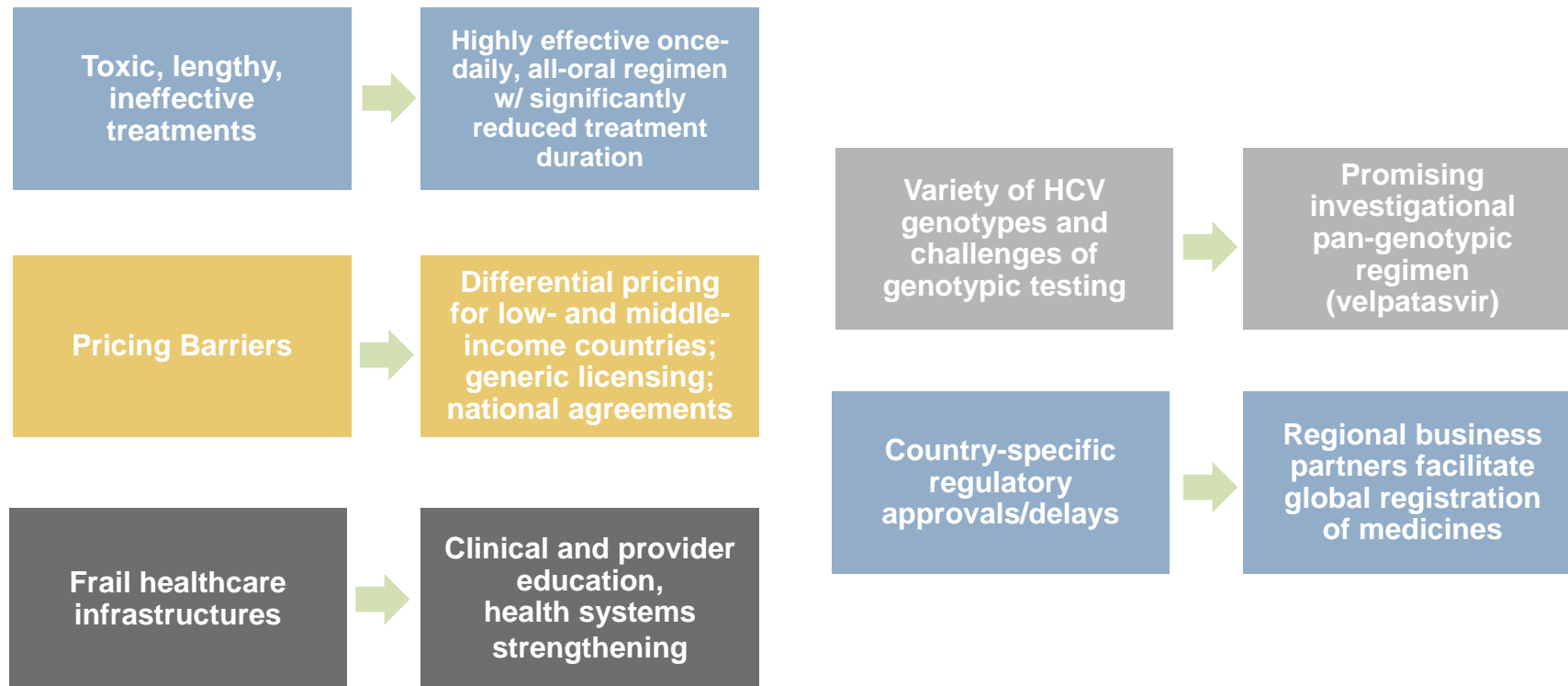
More than **150 million people** worldwide are infected with the hepatitis C virus (HCV), and HCV-related complications cause up to **500,000 deaths** each year.



# New Opportunities for HCV Treatment Expansion

- **First cure:** For the first time, HCV cures are available in short, well-tolerated regimens with high cure rates – provides potential path to hepatitis C elimination.
- **Speed of access:** Gilead is working quickly to enable developing world access to its medicines.
  - Within 10 months of U.S. FDA approval, made Sovaldi® available in Egypt at significantly reduced price
  - Since Oct. 2014, >125,000 Egyptians have begun treatment with Sovaldi; nearly 500 new patients initiate therapy every day
- **Continued research:** Gilead continues to develop treatment options and conduct critical research that can benefit developing world patients.
  - Investigational pan-genotypic therapy (velpatasvir) currently in Phase 3 clinical trials; key to expanding developing world access – would eliminate need for expensive, often unavailable genotypic testing
  - Conducting demonstration projects in several countries (e.g., Rwanda, Georgia, Ukraine) to quantify burden of disease, identify risk factors for transmission, guide future prevention efforts and develop baseline data needed to gauge progress

# Addressing Challenges to HCV Access



## Further Challenges to Tackle

No Dedicated Global Financing for HCV Mono-infection

Lack of Awareness of HCV as a Public Health Threat

Limited Global HCV Advocacy

HCV Testing Not Readily Available in Many Countries

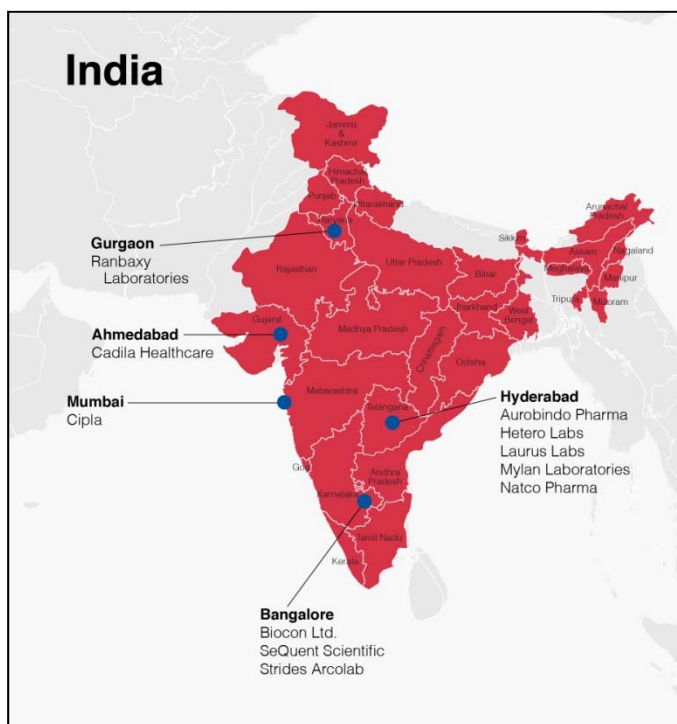
Limited National Resources for HCV

Policy and Stigma that Make It Difficult to Reach Some High-Risk Groups (e.g., IDU)

# Hepatitis C Generic Licensing Partners

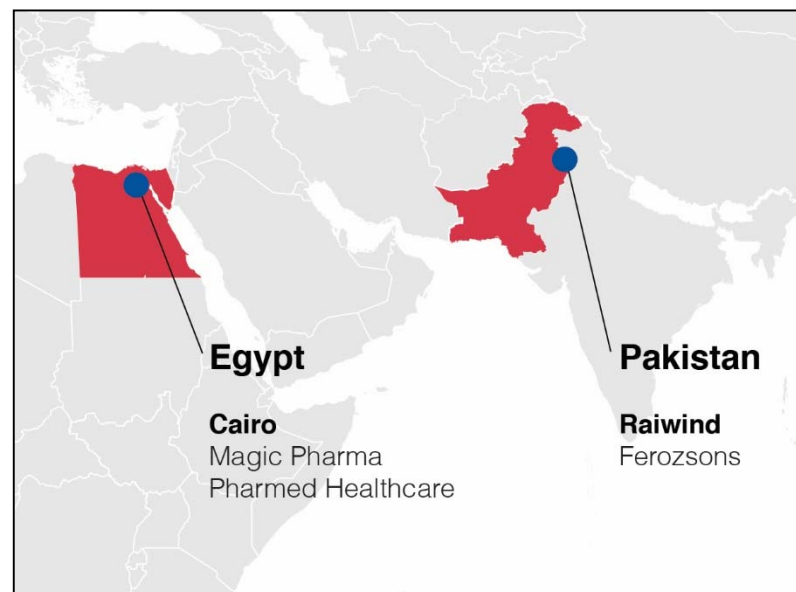
## Eleven International Partners

Produce generic hepatitis C medicines for  
101 resource poor countries



## Three In-Country Partners

Produce generic hepatitis C medicines for  
their home countries



# Reach of HCV Generic Licensing

1. Afghanistan	35. Guinea	69. Palau
2. Algeria	36. Guinea-Bissau	70. Papua New Guinea
3. Angola	37. Guyana	71. Paraguay
4. Antigua and Barbuda	38. Haiti	72. Philippines
5. Bangladesh	39. Honduras	73. Rwanda
6. Benin	40. India	74. Samoa
7. Bhutan	41. Indonesia	75. São Tomé and Príncipe
8. Bolivia	42. Kenya	76. Senegal
9. Botswana	43. Kiribati	77. Seychelles
10. Burkina Faso	44. Kyrgyzstan	78. Sierra Leone
11. Burundi	45. Lao, People's Dem. Rep.	79. Solomon Islands
12. Cambodia	46. Lesotho	80. Somalia
13. Cameroon	47. Liberia	81. South Africa
14. Cape Verde	48. Libya	82. South Sudan
15. Central African Republic	49. Madagascar	83. Sri Lanka
16. Chad	50. Malawi	84. St. Vincent and the Grenadines
17. Comoros	51. Maldives	85. Sudan
18. Congo, Rep.	52. Mali	86. Suriname
19. Congo, Dem. Rep. of the	53. Marshall Islands	87. Swaziland
20. Cook Islands	54. Mauritania	88. Tajikistan
21. Côte d'Ivoire	55. Mauritius	89. Tanzania, U. Rep. of
22. Cuba	56. Micronesia	90. Timor-Leste
23. Djibouti	57. Mongolia	91. Togo
24. Dominica	58. Morocco	92. Tonga
25. Egypt	59. Mozambique	93. Tunisia
26. El Salvador	60. Myanmar	94. Turkmenistan
27. Eritrea	61. Namibia	95. Tuvalu
28. Ethiopia	62. Nauru	96. Uganda
29. Equatorial Guinea	63. Nepal	97. Uzbekistan
30. Fiji	64. Nicaragua	98. Vanuatu
31. Gabon	65. Niger	99. Vietnam
32. Gambia	66. Nigeria	100. Zambia
33. Ghana	67. North Korea	101. Zimbabwe
34. Guatemala	68. Pakistan	

- The **101 countries** in Gilead's generic-eligible territory are home to **more than half** of all people worldwide living with HCV (**103 million** people).
- Territory covers all low-income and nearly all lower-middle-income countries (**65 MICs**).
- Gilead's branded hepatitis C medicines are **available at their lowest prices in all countries** in the expanded generic-eligible territory.



# Access in Action: Egypt



Egypt has the highest HCV prevalence in the world – nearly 15%, by some estimates

## The partnership:

- Ministry of Health implementing ambitious national HCV treatment program; providing care through government clinics and hospitals.
- Gilead provides **branded Sovaldi** to Egyptian Ministry of Health at a significantly reduced price.
- Gilead supports MoH-led HCV medical education and prevention efforts.
- As of June 2015, more than **125,000 patients** have initiated treatment with Sovaldi.
- Will also begin providing Harvoni in November 2015.



*Launch of Egypt's national hepatitis C treatment initiative, October 2014*

# Access in Action: Georgia

Approximately 7% of Georgians are infected with HCV – the third-highest prevalence in the world



## The partnership:

- Ministry of Health, U.S. Centers for Disease Control and Prevention and Gilead collaborating to eliminate hepatitis C in Georgia
- Goal is to demonstrate the impact of widespread HCV **screening and universal treatment** on a national scale
- Ministry of Health leading and implementing the program
- U.S. CDC providing technical support and guidance
- Gilead providing branded Sovaldi and Harvoni at no cost to program; goal of initially treating 5,000 patients in the first year and eventually up to 20,000 patients each year



*A patient participating in the program,  
May 2015*

# Access in Action: Brazil



An estimated 3 million people in Brazil are chronically infected with HCV – but only 10% are currently diagnosed

## The partnership:

- Reached an agreement with the Brazilian Ministry of Health to enable availability of branded Sovaldi through the **national public health system**
- Ministry of Health has committed to scaling up treatment nearly threefold
- Sovaldi also an integral component of Brazil's new **HCV treatment guidelines**
- Gilead also implementing medical education programs to familiarize Brazilian healthcare providers with the latest HCV treatment options



*Brazilian Ministry of Health  
press conference launching new  
treatment guidelines,  
July 2015*

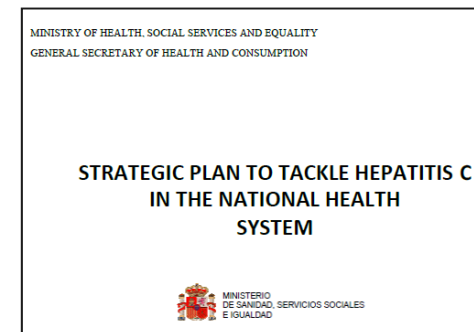
# Access in Action: Spain

Recent reports indicate that Spain has an HCV prevalence of 1.2% – about 472,000 Spaniards



## The partnership:

- In July 2015, Spain's health ministry published a **national strategic plan** to combat hepatitis C
- Includes three DAAs (Harvoni and Viekirax+Exviera), with a cap of €786 million to treat 51,900 patients over three years
  - After cap is reached, health ministry will resume negotiation with drug makers
- Spain's finance ministry has established **innovative regional loans** to fund HCV treatment:
  - Very low interest rates
  - 10 years to repay loans, with two-year grace period
  - HCV treatment loans do not count toward regional debts
- Regions will report monthly number of patients treated to national health ministry



# Q&A

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