Expanding Chronic Hepatitis C Treatment in Low- and Middle-Income Countries

Gilead’s Treatment Access Commitment

Gilead works to enable access to its medicines for all people who can benefit from them, regardless of where they live or their economic means. In developing countries, approximately 8 million patients now receive Gilead-based HIV therapies as a result of collaborations with governments, generic manufacturers, regional business partners, policy makers, healthcare providers, patient groups and public health entities.

Gilead is now pursuing multiple strategies to expand access to its chronic hepatitis C virus (HCV) medicines in low- and middle-income countries, prioritizing those with the greatest disease burden. More than 150 million people worldwide are infected with HCV, and HCV-related complications cause up to 500,000 deaths each year.

1. Pricing

- **Flat Pricing**
  - Suggested public/government price for Sovaldi® ($300/bottle) and Harvoni® ($400/bottle) across all low-income and nearly all lower-middle-income countries
  - Pricing reflects approximately 98% discount relative to U.S.
  - Reflects minimal profit that is re-invested in support activities

- **Tiered Pricing**
  - Significantly discounted pricing for all other middle-income countries, based on GNI per capita and disease burden
  - Prices negotiated on country-by-country basis

2. Generic Licensing

- **International**
  - India-based partners licensed to produce generics for 101 countries home to >50% of HCV burden
  - Includes investigational pan-genotypic combination of sofosbuvir/velpatasvir (pending approval)
  - Minimal royalty
  - Fosters competition to drive down prices

- **In-Country**
  - Agreements with local generic manufacturers in countries with heavy HCV burden (e.g. Egypt and Pakistan)
  - Designed to further accelerate access by increasing supply and competition

3. Registration & Business Partnerships

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4. Research

- **International Clinical Collaborations**
  - Clinical trials in broad patient populations across all genotypes
  - On-going or planned studies in Brazil, China, Egypt, Ethiopia, Gambia, India, Mongolia, the Philippines, Senegal, South Africa, Tanzania, Thailand and Vietnam
  - Supporting numerous in-country research programs and demonstration projects

5. Country & NGO Partnerships

- **Targeted Initiatives for High-Risk Groups**
  - Supporting civil society efforts to reach IDUs and other high-risk groups with education, screening and care
  - Example: Ukraine pilot program providing treatment to IDUs and other affected populations

- **Country & NGO Partnerships**
  - Register medicines with regulatory authorities
  - Coordinate distribution with local governments and pharmacies
  - Track orders and inventory to prevent supply disruptions
  - Conduct safety reporting

6. Policy

- **Fostering Global Support**
  - Advocating for domestic and international funding for public health initiatives and policies to diagnose, treat and cure patients, and to prevent new infections
  - Ensuring Gilead HCV medicines are included on the WHO Essential Medicines List

www.gilead.com/responsibility