Gilead is working to enable access to its medicines for all people who can benefit from them, regardless of where they live or their economic means.

### Snapshot

| Gilead has agreements with 11 Indian companies to manufacture generic hepatitis C medicines for **101 developing countries** | There are **103 million** people living with hepatitis C in these developing countries | Gilead also offers its branded hepatitis C medicines at a **significantly reduced flat price** in these countries |

For more than a decade, Gilead has been working in partnership with governments, healthcare systems, providers, public health entities and generic manufacturers to make its HIV and hepatitis B medicines available worldwide. Currently, 8 million people living with HIV in developing countries receive Gilead antiretroviral medicines through these efforts. Gilead is now working to help ensure broad access to its hepatitis C medicines in developing countries.

Gilead has signed agreements with 11 India-based generic pharmaceutical manufacturers to develop sofosbuvir, the single tablet regimen of ledipasvir/sofosbuvir and the investigational single tablet regimen of sofosbuvir/velpatasvir for distribution in 101 developing countries. Gilead has also signed agreements with three local generic manufacturers for in-country production and distribution of our hepatitis C medicines in Egypt and Pakistan.

### Generic Agreements

Under the licensing agreements, Gilead’s Indian generic manufacturing partners have the right to develop and market generic versions of Gilead HCV medicines in certain developing countries. The generic drug companies may set their own prices and receive a complete technology transfer of the Gilead manufacturing process, enabling them to scale up production as quickly as possible. Licensees also pay a royalty to Gilead that supports overall developing world product registration, medical education and training, safety monitoring and other business activities.

### International Licensees

- Aurobindo Pharma Ltd.
- Biocon Limited
- Cadila Healthcare Ltd.
- Cipla Ltd.
- Hetero Labs Ltd.
- Laurus Labs Pvt. Ltd.

### In-Country Licensees

- Mylan Laboratories Ltd.
- Natco Pharma Ltd.
- Ranbaxy Laboratories Ltd.
- Sequent Scientific Ltd.
- Strides Arcolab Ltd.
- Ferozsons Laboratories Ltd. (Pakistan)
- Magic Pharma (Egypt)
- Pharmed Healthcare (Egypt)
Chronic Hepatitis C Treatment Expansion Challenges

Providing hepatitis C treatment in resource-limited settings presents complex challenges. For example, many countries have limited or no hepatitis C screening, lack the healthcare infrastructure to care for significant numbers of patients and do not have the diagnostic capacity to test for the diverse range of genotypes requiring different treatment regimens. Public and policymaker awareness of the disease is limited, as is national and international funding for hepatitis C screening and treatment.

Working Locally to Advance Access

Generic manufacturing is just one component of scaling up hepatitis C treatment. Also critical are in-country activities that support drug availability and use, including product registration, medical and clinical education, demand forecasting and collaborative research. Gilead works with a global network of regional business partners on these activities.

- **Product Registration**: Gilead invests considerable resources to register its hepatitis products with regulatory authorities in each developing country included in its access programs. Regional business partners help manage national registration processes, which can vary widely across countries, and assist with pharmacovigilance and safety reporting once registrations are obtained.

- **Public Health and Medical Education**: Gilead and regional business partners conduct public health and medical education events with doctors and other healthcare providers in developing countries, to increase their knowledge of disease burden and impact, as well as viral hepatitis treatment options and their appropriate use for patients.

- **Demand Forecasting**: Ensuring an uninterrupted supply of medicine requires accurately forecasting product demand. Gilead has invested in proprietary information tools to track orders and inventory across regions and prevent disruptions in supply.

- **Collaborative Research**: National trials for sofosbuvir are underway or planned in several developing countries.

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