CHRONIC HEPATITIS C TREATMENT EXPANSION
Generic Manufacturing for Developing Countries

Gilead is committed to increasing access to its medicines for all people who can benefit from them, regardless of where they live or their ability to pay.

Snapshot

Gilead has signed an agreement with seven Indian companies to manufacture generic hepatitis C medicines for **91 developing countries**

There are more than **100 million** people living with hepatitis C in these developing countries

Gilead is also working to expand access to its hepatitis medicines through **tiered pricing in developing countries**, differential pricing for public and private markets and partnerships with national governments

Since 2003, Gilead has been working in partnership with governments, healthcare systems, providers and public health entities to make its HIV and hepatitis B medicines available worldwide. Currently, six million people living with HIV in developing countries are accessing Gilead's antiretroviral medicines through these efforts. Gilead is now working to help ensure broad access to its hepatitis C medicines in developing countries.

In September 2014, Gilead signed an agreement with seven India-based generic pharmaceutical manufacturers to develop sofosbuvir and the single tablet regimen of ledipasvir/sofosbuvir for distribution in 91 developing countries.

Generic Agreements

Under the licensing agreement, Cadila Healthcare Ltd., Cipla Ltd., Hetero Labs Ltd., Mylan Laboratories Ltd., Ranbaxy Laboratories Ltd., Sequent Scientific Ltd. and Strides Arcolab Ltd. have the right to develop and market generic sofosbuvir and ledipasvir/sofosbuvir in certain developing countries. The companies may also develop combinations of sofosbuvir or ledipasvir with other hepatitis C medicines. The generic drug companies may set their own prices and will 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 (7 percent) that will support overall developing world product registration, medical education and training, safety monitoring and other business activities.

The licensing agreement encompasses the following countries:

Afghanistan	Chad	Guatemala	Maldives	Papua New Guinea	Swaziland
Angola	Comoros	Guinea	Mali	Rwanda	Tajikistan
Antigua and Barbuda	Congo, DR	Guinea-Bissau	Mauritania	Samoa	Tanzania
Bangladesh	Congo, Rep.	Guyana	Mauritius	Sao Tome & Pr.	Timor Leste
Benin	Cote d'Ivoire	Haiti	Mongolia	Senegal	Togo
Bhutan	Cuba	Honduras	Mozambique	Seychelles	Tonga
Bolivia	Djibouti	India	Myanmar	Sierra Leone	Turkmenistan
Botswana	Dominica	Indonesia	Namibia	Solomon Islands	Tuvalu
Burkina Faso	Egypt	Kenya	Nauru	Somalia	Uganda
Burundi	Equatorial Guinea	Kiribati	Nepal	South Africa	Uzbekistan
Cambodia	Eritrea	Kyrgyz Republic	Nicaragua	South Sudan	Vanuatu
Cameroon	Ethiopia	Lao PDR	Niger	Sri Lanka	Vietnam
Cape Verde	Fiji	Lesotho	Nigeria	St. Vincent and the Grenadines	Zambia
Central African Republic	Gabon	Liberia	North Korea	Sudan	Zimbabwe
	Gambia	Madagascar	Pakistan	Suriname	
	Ghana	Malawi	Palau		

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.

> *"Curative treatments that are more efficacious and less toxic than ever before have the potential to dramatically reduce the health and economic burdens associated with HCV infection around the world. The opportunity to address the massive HCV pandemic is now within reach and a global movement is needed to create generalized access to HCV treatment in high-, middle- and low-income countries. This will require political will, financial investment, and support from pharmaceutical, medical and civil society organizations around the world."*
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> – WHO Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection, 2014

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.
- *Medical and Clinical Education*: Gilead and regional business partners conduct medical and clinical education events with doctors and other healthcare providers in developing countries, to increase their knowledge of 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 Sovaldi® are underway or planned in several developing countries where they are required for regulatory approval, including India and Vietnam.