CHRONIC HEPATITIS C TREATMENT EXPANSION
Generic Manufacturing for Developing Countries

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, 7.6 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.
Mylan Laboratories Ltd.
Natco Pharma Ltd.
Ranbaxy Laboratories Ltd.
Sequent Scientific Ltd.
Strides Arcolab Ltd.

In-Country Licensees

Ferozsons Laboratories Ltd. (Pakistan)
Magic Pharma (Egypt)
Pharmed Healthcare (Egypt)

The licensing agreement encompasses the following countries:

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

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.

> *"Curative treatments that are more efficacious and less toxic than ever before have the potential to dramatically reduce the healt h 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