

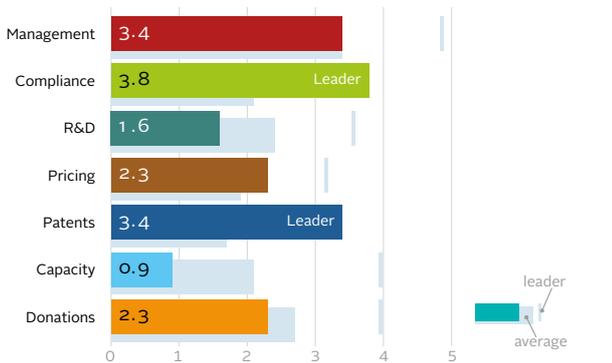
RANK	SCORE
8▼	2.45
5 (2014)	

# Gilead Sciences Inc.

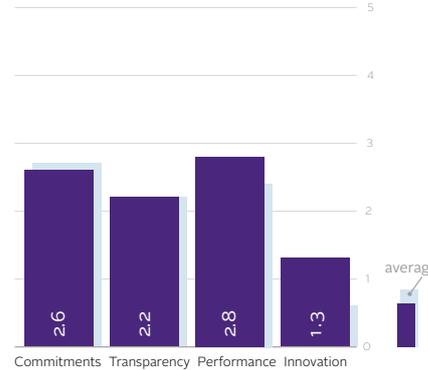


Stock Exchange: XNAS • Ticker: GILD • HQ: Foster City, CA, US • Employees: approx. 8,000

## Ranking by technical area



## Ranking by strategic pillar



## PERFORMANCE

Gilead drops to 8th place, despite being a leader in key areas, including in Patents & Licensing. It has pioneered the use of non-exclusive voluntary licensing beyond HIV/AIDS, and its solid compliance processes protect it from breaching laws and regulations on unethical behaviour. Its new donation programme aims to eliminate hepatitis C virus (HCV) in Georgia. Yet, in R&D, its performance remains low: its relevant pipe-

line is smaller than the industry average, and it lags in ensuring ethical clinical trial conduct and on clinical data transparency. It falls in pricing, despite leading in certain metrics. It does not, for example, clearly make sales agents accountable or facilitate products' rational use. Gilead has few capacity building activities, focusing on manufacturing, and limited targeting of local gaps.

## CHANGE SINCE 2014

- Maintains a low level of transparency regarding its stakeholder engagement activities.
- Maintains high standards of ethical behaviour: once again, it has not been found to have breached laws or regulations relating to unethical behaviour.
- Maintains comparatively poor approaches for ensuring clinical trials are conducted ethically and for sharing clinical trial data.
- Has more products with equitable pricing strategies than in 2014.
- No longer provides volume-of-sales information.
- Confirms its leadership in Patents & Licensing, having voluntarily agreed non-exclusive licences for all on-patent products for high-burden communicable diseases.
- Has launched a new donation programme aimed at the elimination of hepatitis C in Georgia.

## OPPORTUNITIES

**Expand into access strategies for non-communicable diseases.** Gilead can apply its access approach for HIV/AIDS and hepatitis C products to its portfolio for non-communicable diseases (NCDs) (e.g., ranolazine (Ranexa®), a second-line treatment for stable angina). This could help address the increasing burden of these conditions in low- and middle-income countries.

**Expand licensing approach to more middle income countries.** Gilead can consider ways of including more high-prevalence middle income countries in the terms of its hepatitis C licensing arrangements, through, for example, tiered licensing policies.

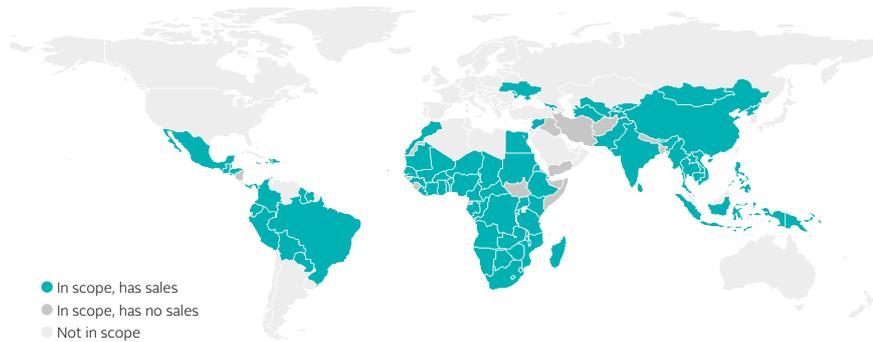
**Share results and lessons learned from donation programme.** Gilead's donation programme for hepatitis C is the first to aim to eliminate this virus. As such, insight into its progress and impact is particularly important to share. Gilead can rigorously monitor and evaluate the drug donation programme it has initiated in Georgia, and then publish its results and lessons learned.

**Ensure affordability of products worldwide.** Gilead can expand its consideration of socio-economic factors in its inter-country equitable pricing strategies, to help ensure products are globally affordable for different populations. The company can mitigate the risk of mark-ups on HIV/AIDS products by providing pricing guidelines to sales agents.

**Expand training approach.** Gilead can draw from its experience in compliance training to build capacities of third parties in more areas, taking local needs and capacity gaps into account.

**Improve clinical trial transparency.** Gilead lags behind the industry in this area. It can ensure its policy for clinical trial data transparency sets out a timeline for publishing results and a protocol for publishing all results, regardless of outcome. The company can also introduce a mechanism for sharing anonymised patient-level data with third parties.

Sales in countries in scope



SALES AND OPERATIONS

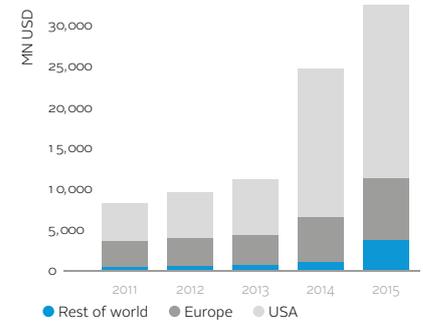
Gilead is a biopharmaceutical company that operates through one segment: Human Therapeutics. It focuses on HIV/AIDS, liver diseases, haematology and oncology, inflammatory and respiratory diseases and cardiovascular conditions. In 2015, the company announced the acquisition of EpiTherapeutics, a leader in epigenetics.

Gilead markets products in 93 countries within the scope of the Index. The company's sales have grown steadily since 2014.

Revenues by segment (2015)



Revenues by geographic region

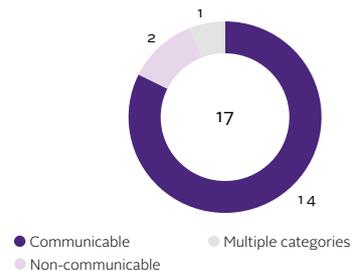


PORTFOLIO AND PIPELINE

Gilead's has a relatively small portfolio, with 17 medicines for diseases in scope. It has a relatively small pipeline, with 13 R&D projects, that addresses the needs of people in countries in scope.

Several of Gilead's products have gained marketing authorisation from the FDA since 2014, including: elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya®) for HIV-1 in 2015, and sofosbuvir/ledipasvir (Harvoni®) for chronic hepatitis C genotype 1, 4, 5 or 6 infection.

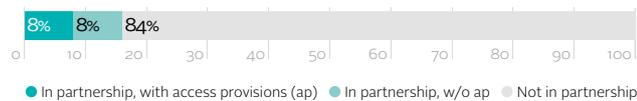
Products per disease category



Gilead's portfolio is heavily focused on HIV/AIDS and viral hepatitis. Out of the 17 products in its relevant portfolio, 14 target these diseases.

Its portfolio and pipeline are heavily focused on HIV/AIDS and viral hepatitis, which are the targets of 14 of Gilead's medicines. A relatively large proportion of Gilead's pipeline targets high-priority product gaps with low commercial incentive, for example fixed-dose combinations (FDCs) for hepatitis C genotypes 4, 5 and 6.

Pipeline projects



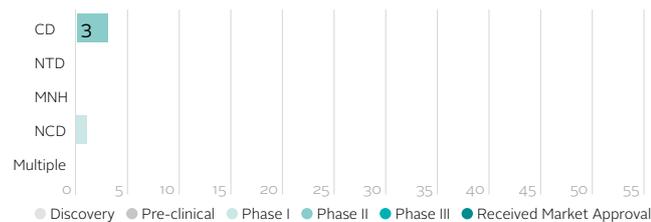
With Johnson & Johnson, Gilead is developing two fixed-dose combinations for HIV/AIDS. Whether they can be produced under Gilead's licensing agreements will depend on the patent status of the regimens' other compounds.

First-line treatments and essential medicines



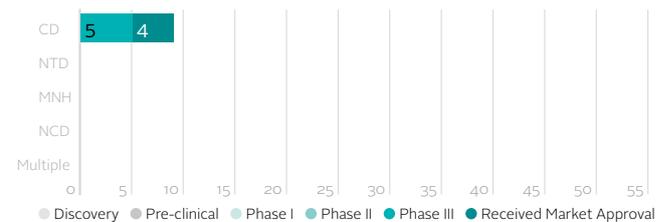
Approximately half its products are on the WHO EML and/or are first-line: e.g., sofosbuvir (Sovaldi®), tenofovir disoproxil fumarate (Viread®), and efavirenz/emtricitabine/tenofovir disoproxil fumarate (Atripla®).

Pipeline by stage of development



Gilead has several innovative medicines in clinical development, targeting hepatitis B virus (HBV), HIV/AIDS and chronic obstructive pulmonary disease (COPD). Presatovir, targeting respiratory syncytial virus, is in phase II trials.

Adaptive medicines and vaccines



Gilead's pipeline includes fixed-dose combinations for HIV/AIDS and hepatitis C. In January 2016, it applied to the FDA for the approval of tenofovir alafenamide as a once-daily treatment for chronic HBV.

# Gilead Sciences Inc.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 12 SCORE 3.4

**Drops out of top 10, as peers overtake.** Gilead falls three places, despite having a range of access initiatives and a solid performance management system. It does not publish information related to its stakeholder engagement activities.

**Multiple access approaches.** Gilead uses a series of approaches to improve access to medicine, such as pricing, generic licensing, health systems strengthening, registration and partnerships with NGOs and in R&D.

**Above average measuring and reporting on access outcomes.** Gilead is transparent about its access-related commitments, targets and performance measurements. It has a centralised performance management system with quarterly reviews. The company has a broad strategy to incentivise employees to work toward access-related goals, all financial in nature.

**Low transparency on stakeholder engagement strategy and activities.** Gilead has a clear stakeholder engagement strategy, but does not provide information regarding the stakeholder engagement activities of its branch organisations. Furthermore, the company does not publish information about its global stakeholder engagement activities.

### MARKET INFLUENCE & COMPLIANCE

RANK 1 SCORE 3.8

**Leader in market influence and compliance.** Gilead once again ranks 1st in this area. It has a strong compliance system, including guidance and contractual obligations to contractors. In an innovative move, the company has developed a compliance guide for third parties.

**Mixed performance in ethical marketing and anti-corruption.** Gilead has an ethical marketing code that also applies to third parties, but it has no performance incentives other than sales targets. Furthermore, Gilead does not disclose its marketing activities and payments in countries within scope. The company is not a signatory to the UN Global Compact.

**Publicly discloses policy positions and conflict of interest policy.** Gilead publishes its policy positions related to access, in particular those

related to the responsible use of intellectual property, and trade issues. The company also states that it makes no political contributions in countries in scope. In the company's Code of Ethics, Gilead discloses the details of its policy for managing conflicts of interest.

**No breaches of laws or codes of conduct governing ethical behaviour.** As in 2014, Gilead has not been the subject of any settlements for criminal, civil or regulatory infractions relating to unethical marketing or corruption anywhere in the world during the period of analysis.

**Business Conduct team dedicated to managing ethical behaviour and access.** Gilead's access-to-medicine group has its own dedicated Business Conduct team that covers interactions in Latin America, Africa, Asia and the Pacific. All employees must undergo training in this respect and understand all the various elements of the company's business conduct manual.

► **Innovation: compliance guidance and training for third parties.** Gilead adopted a Regional Business Partner Compliance Pocket Guide, which addresses a range of interactions with physicians and government officials. Gilead offers compliance training, featuring case-based scenarios, to business partners across multiple regions. In addition, Gilead has developed an auditing programme for its partners.

### RESEARCH & DEVELOPMENT

RANK 16 SCORE 1.6

**Continues to perform below par, particularly regarding trial data transparency and trial conduct.** Gilead's relevant pipeline is smaller than the industry average, and it falls below industry standards for clinical trial conduct and clinical data transparency.

**Lack of clear strategies for operationalising R&D commitments.** The company has committed to conducting R&D for resource-limited settings. However, it does not provide evidence that it has measurable time-bound strategies for ensuring its commitments are achieved.

**Poor measures to ensure clinical trials are conducted ethically.** Despite having policies in place to ensure ethical clinical trial conduct, Gilead does not provide evidence that it monitors clinical trial conduct or takes disciplinary action when ethical violations occur.

**Lags behind in clinical trial data transparency.** Gilead has no policy on publishing clinical trial results within a given timeframe, nor of publishing trial results regardless of outcome. It is the only company in the industry that does not have a systematic mechanism for providing scientific researchers with access to anonymised patient-level data on request.

**Does not share intellectual property.** The company did not provide evidence of sharing intellectual property with research institutions or neglected-disease drug-discovery initiatives.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 7 SCORE 2.3

**Gilead drops six places, but remains among the leaders.** Gilead falls from 13th to 7th. Although it performs well in key areas, it does not perform consistently across all dimensions, including equitable pricing, setting pricing guidelines for sales agents or in facilitating products' rational use. It is less transparent than in 2014 about its volumes of sales, which means there is little evidence for the implementation of its pricing strategies. Its inter-country equitable pricing strategies only consider a few socio-economic factors.

**Commits to registering products within a set timeframe.** Gilead is the only company that commits to registering products for most of the diseases in scope (where it is active) in most low-income and lower-middle income countries and within 12 months after gaining the first market approval. The company has filed to register half (50%) of its newest products in a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). However, most of these products gained marketing authorisation quite recently: some only in 2015 and 2016.

**Monitors prices and provides pricing guidelines for some products.** Gilead monitors the selling price and mark-ups of its HIV/AIDS medicines in all applicable countries. For its hepatitis C products, the company sets pricing guidance for its sales agents via transfer prices.

**Consistent recall guidelines.** Gilead has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Gilead has not recalled

a product for a relevant disease in a country in scope during the period of analysis. It states that it does make recall information publicly available.

**Does not adapt brochures or packaging to facilitate rational use.** Gilead does not provide evidence that it adapts its brochures or packaging materials to address the needs of local populations, e.g., in terms of language, literacy levels, environmental conditions, demographic or cultural needs.

**Targets countries with a high need for access.** Most of Gilead's products target most of the countries with the highest need for access: it has the highest proportion of products (50%) with equitable pricing strategies that target the majority of priority countries (disease-specific sub-sets of countries with high need for access to relevant products). Together, these strategies reach 77% of corresponding priority countries. They cover products for HIV/AIDS and hepatitis C. Gilead now has more products with equitable pricing strategies than in 2014.

► **Best practice: high transparency of products' registration status.** Gilead is the only company to publish the registration status of the majority of its products for high-burden diseases in full detail, including when and where the product was filed for registration, and whether it has been approved.

## PATENTS & LICENSING

RANK 1 SCORE 3.4

**Maintains top rank in Patents & Licensing.** This is due to its consistent approach to supporting affordability and supply of its patented portfolio through licensing, and to its innovative application of licensing outside of the HIV/AIDS space.

**Continuing engagement in voluntary licensing.** Gilead continues to pursue a broad licensing approach for its patented in-scope products. Its licensing agreements include access-oriented terms, and cover a comparatively high number of middle income countries with high HIV/AIDS or HCV prevalence.

► **Best practice: licensing all on-patent products in scope for high-burden diseases.** Gilead licenses all of its patented products for high-burden communicable diseases, including agreements made bilaterally and via the Medicines Patent Pool. It licenses products pre-registration, publicly discloses the agreements, includes access-oriented terms, and includes a comparatively high number of middle-income countries with high prevalences of the disease in question (either HIV/AIDS or hepatitis C).

► **Innovation: licensing beyond HIV/AIDS.** Gilead has made the significant step of licensing products outside of the HIV/AIDS space, to include hepatitis C products. It has applied licensing to

all of its hepatitis C portfolio. Notably, it did so prior to registering the products.

## CAPACITY BUILDING

RANK 18 SCORE 0.9

**Limited focus on capacity building overall.** Gilead's performance drops in 2016. The company builds manufacturing capacity in countries in scope, but with few activities in the other areas measured by the Index (including R&D and supply chain management). Its targeting of local needs and capacity gaps is limited.

**Above average in building manufacturing capacity.** Gilead makes a general commitment to building manufacturing capacity in relevant countries. In the period of analysis, the company undertook a number of technology transfers with licensees for its HIV/AIDS and hepatitis C medicines.

**Limited focus on strengthening pharmacovigilance systems.** Gilead routinely updates safety labels for its products in countries in scope. However, the company did not disclose voluntary safety data sharing with authorities, or external capacity building activities (such as training partnerships) to strengthen pharmacovigilance systems in countries in scope.

**Below average in building capacity outside the value chain.** Gilead's philanthropic strategy is relatively weak: it targets local needs but does not aim for measurable, sustainable objectives. The company discloses one relevant initiative – HiV-Link – to build HIV/AIDS treatment capacities in rural areas of Ethiopia and Uganda.

**Weak performance in building R&D and supply chain management capacity.** Gilead did not disclose any relevant activities to build R&D capacity or strengthen supply chains in countries in scope during the period of analysis.

## PRODUCT DONATIONS

RANK 13 SCORE 2.3

**Gilead remains a mid-ranking company.** It maintains its long-term donation programmes for visceral leishmaniasis and HIV/AIDS, and in a new programme to eliminate hepatitis C in Georgia.

**Commits to supporting WHO's leishmaniasis control program.** Gilead committed to donating 380,000 vials of amphotericin B liposome for injection (AmBisome®) over the next five years for a WHO control programme for visceral leishmaniasis. Gilead's donations to the programme started in 2011.

**Does not disclose its donation policy.** Gilead states that all its donations adhere to WHO Inter-Agency Guidelines. However, it did not disclose its donation policies.

**Monitoring mainly the responsibility of partners.** Gilead contractually requires that donation recipients have monitoring systems in place. The company receives regular reports on donated products.

**Donates generic HIV/AIDS medicines annually.** Gilead donates generic emtricitabine/tenofovir disoproxil fumarate and efavirenz/emtricitabine/tenofovir disoproxil fumarate each year to Uganda Cares and HardtHaven (a Ghanaian orphanage for children who are HIV-positive). Gilead purchases these products from Mylan.

► **Innovation: launched a hepatitis C donation programme.** In April 2015, Gilead launched an innovative donation programme with the goal of eliminating hepatitis C virus in Georgia. The programme includes universal screening and treatment, prevention and surveillance. The company provided 5,000 free courses of sofosbuvir (Sovaldi®) to the government of Georgia, and will provide 20,000 free courses of sofosbuvir/ledipasvir (Harvoni®) per year.