

RANK	SCORE
13▼	2.29
8 (2016)	

# Gilead Sciences Inc.

Stock Exchange: NASDAQ • Ticker: GILD • HQ: Foster City, California, United States • Employees: 10,193

## PERFORMANCE

Falls 5 places to 13<sup>th</sup> due to a comparatively poor performance in governance and compliance. It maintains a strong performance in some areas, for example, in its licensing strategy and its application of equitable pricing strategies across a high proportion of its products.

**Management:** Falls 6 places to 18<sup>th</sup>. It does not have direct board responsibility for its access approach, and does not commit to measuring the impact of its access initiatives.

**Compliance:** Falls 15 places to 16<sup>th</sup>. Comparatively poor performance, with below-average transparency and lacking components of an internal control system looked for by the Index.

**R&D:** Falls 2 places to 18<sup>th</sup>. Gilead performs on average in access planning, lags in R&D investment transparency and performance, and lacks a public policy for post-trial access.

**Pricing:** Rises 5 places to 2<sup>nd</sup>. Strong registration commitment and transparency, with a leading performance in the application of equitable pricing strategies.

**Patents:** Falls 2 places to 3<sup>rd</sup>. Leading performance in its licensing approach compared to peers, but falls in patent filing/enforcement policy.

**Capacity:** Rises 5 places to 13<sup>th</sup>. Improves performance against new metrics, with initiatives in three areas of Capacity Building.

**Donations:** Rises 2 places to 11<sup>th</sup>. Maintains three donation programmes focused on NTDs, but fails to provide evidence of its sustainability.

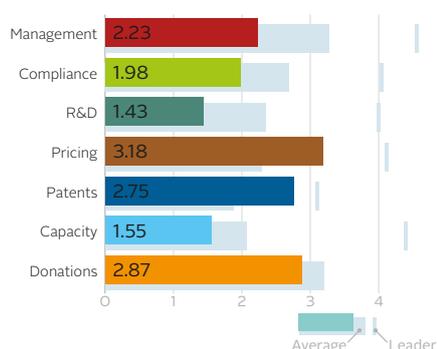
## OPPORTUNITIES

**Expand access plans across pipeline.** Gilead has an opportunity to develop a pipeline-wide approach to planning for access. For example, Gilead's access planning process currently focuses on HIV/AIDS and hepatitis B and C. The company can also expand such planning to R&D projects for projects targeting communicable diseases, including presatovir for the treatment of RSV, and non-communicable diseases, including three late-stage oral anti-cancer agents.

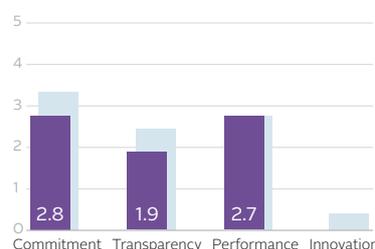
**Strengthen transparency, policies and procedures to ensure compliance.** Gilead falls behind peers due to overall lack of transparency across the Market Influence and Compliance Technical Area. Gilead can publicly disclose which stakeholder groups (e.g., patient groups in countries in scope) the company participates in and whether it provides financial support to such groups. The company can also publicly disclose whether political contributions have been made in low- and middle-income countries. The company can improve its internal control framework to ensure compliance through the implementation of a fraud-specific risk assessment, and procedures to segregate duties. It can also help improve responsible sales practices by decoupling sales incentives from sales targets.

**Expand access further by maximising effectiveness of licensing approach.** Gilead consistently applies inter- and intra-country equitable pricing strategies and licensing approaches across its portfolio. Gilead can maximise the effectiveness of its licensing-based approach by reviewing generic company activity in countries within the scope of agreed licences where Gilead does not have sales. In cases where generic company activity is absent/limited, Gilead can consider proactively registering and pricing equitably within these countries to facilitate competition and access, or by identifying mechanisms within licences to incentivise generic market entry. Gilead commits to filing its newest products in scope for registration in countries in scope within 12 months of first market approval.

### Performance by technical area



### Performance by strategic pillar



### CHANGE SINCE 2016

- Developed a comprehensive process to develop access plans for all R&D projects targeting HIV/AIDS, viral hepatitis B and C and leishmaniasis during development.
- Launched the Gilead Public Health Award: Viral Hepatitis Program in 2017 to provide research grants to researchers in low- and middle-income countries focused on viral hepatitis care and treatment.
- Joined the MenStar Coalition that was launched in 2018 and aims to improve diagnosis and treatment of HIV in men, particularly in sub-Saharan Africa.
- Expanded its HIV licences signed with the MPP to include three additional countries with the inclusion of Malaysia and Ukraine as middle-income countries within the scope of the Index.
- Received FDA approval for the first pangenotypic hepatitis C treatment, sofosbuvir/velpatasvir (Epclusa®) in June 2016, followed by FDA approval for the second, sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) in July 2017.

**PIPELINE** for diseases and countries in scope

**Comparatively small pipeline:** 22 R&D projects (all medicines) for diseases in scope.

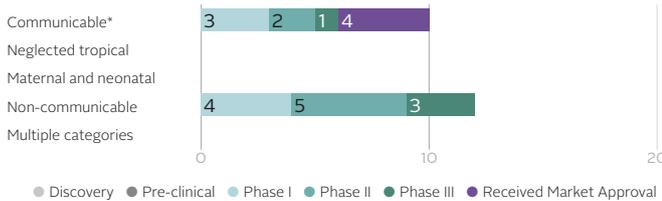
**Clinical candidates:** 18, including remdesivir for the treatment of Ebola and emtricitabine and tenofovir alafenamide (Descovy®) for HIV pre-exposure prophylaxis.

**Regulatory approvals:** 4, including sofosbuvir/velpatasvir (Epclusa®) for the treatment of hepatitis C virus (pan-genotypic).

**R&D focus:** non-communicable diseases (cancer) and communicable diseases (HIV/AIDS and viral hepatitis B and C)

**Access provisions:** for 8 projects, all with registration and equitable pricing strategies and plans for non-exclusive voluntary licensing and WHO prequalification.

**Projects in the pipeline: 22**



Gilead's Phase I clinical candidate remdesivir was one of a select few experimental treatments recommended by a WHO expert review panel for use in the 2018 Ebola outbreak in the Democratic Republic of Congo.

**Projects for R&D priority targets with access provisions: 4**



Of Gilead's 22 R&D projects, eight are supported by access provisions: e.g., emtricitabine/tenofovir alafenamide (Descovy®) for HIV pre-exposure prophylaxis includes registration and equitable pricing strategies, among others. Five of its 15 late-stage projects have provisions.

**PORTFOLIO** for diseases and countries in scope

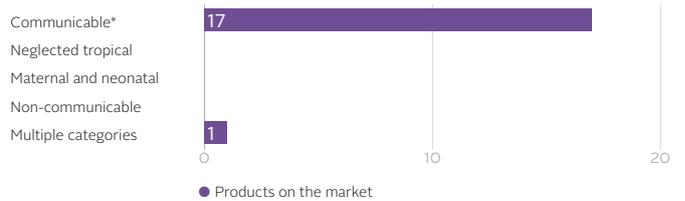
**Comparatively small portfolio:** 18 products (all medicines) for diseases in scope.

**Portfolio focus:** communicable diseases (HIV/AIDS and viral hepatitis B and C).

**Essential medicines:** 44% of Gilead's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

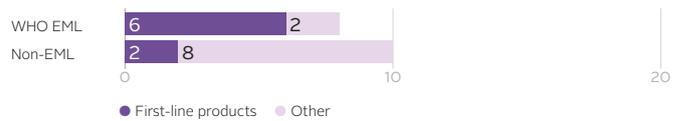
**First-line treatments:** 44% of Gilead's medicines have first-line indications for diseases in scope.

**Products on the market: 18**



Gilead's portfolio includes products such as bicitegravir/emtricitabine/tenofovir alafenamide (Biktarvy®) and the pharmacokinetic booster cobicistat (Tybost®), both used in the treatment of HIV/AIDS.

**Essential medicines with first-line indications: 6**



56% of Gilead's medicines are listed on the WHO EML and/or as first-line treatments: e.g., liposomal amphotericin B (AmBisome®) and tenofovir alafenamide (Vemlidy®).

**BUSINESS CONTEXT**

**One business unit:** Human Therapeutics, which has five therapeutic areas (HIV/AIDS, liver diseases, haematology and oncology, inflammatory and respiratory diseases and cardiovascular diseases).

**M&A news:** 2017 acquisition of Kite Therapeutics, specialising in cancer immuno-

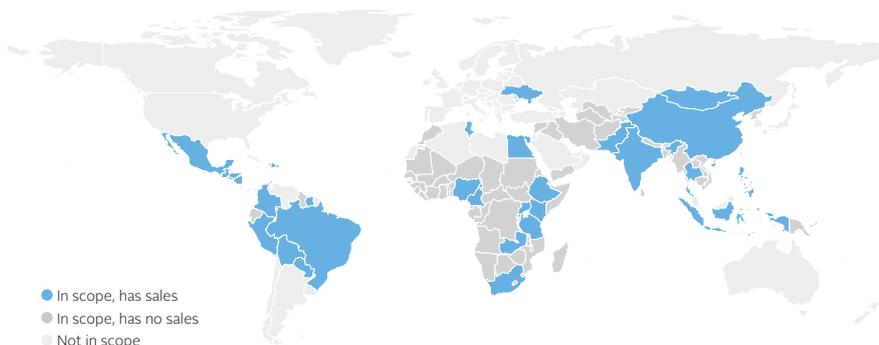
therapy products; acquisition of Cell Design Labs, Inc., specialising in cell-based therapies for cancer and other diseases.

**Presence in emerging markets:** In 2018, Gilead reports sales in 32 countries in scope.

**Revenue by segment (2017) - USD**

Medicines (Product)	26,107 MN
Total	26,107 MN

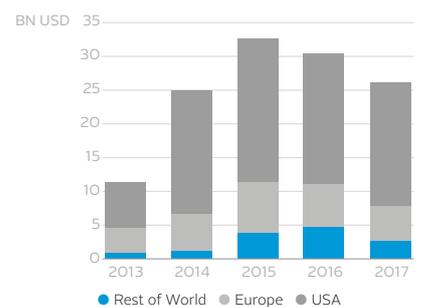
**Sales in countries in scope**



Statistics relate only to diseases and countries in scope.

\* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.  
 \*\* See Appendix IV for definition.

**Revenue by geographic region**



# Gilead Sciences Inc.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 18 SCORE 2.23

**Has an access-to-medicine strategy with executive-level responsibility.** Gilead has an access-to-medicine strategy with a business rationale. The strategy focuses on pricing and licensing approaches to improve access to the company's HIV and viral hepatitis products, in countries where the burden is comparably high. The highest level of responsibility for access sits with an executive committee member.

**Financial access-related incentives in place for employees.** Gilead has financial incentives in place to motivate employees to perform on access-related issues. These incentives include bonuses relating to performance rates.

**Measures and monitors outcomes and progress; not impact.** Gilead measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments, objectives and targets. For example, for the PEPFAR-led DREAMS initiative, the company reports reaching millions of people living with HIV/AIDS in developing countries with its medicines. However, it does not report measuring the impact of its initiatives.

**Limited transparency about stakeholder engagement.** Gilead performs relatively poorly when it comes to the disclosure of its stakeholder engagement. It discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. Gilead has, however, internal guidelines for incorporating the views of local stakeholders.

### MARKET INFLUENCE & COMPLIANCE

RANK 16 SCORE 1.98

**Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards.** Gilead has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. The company does not disclose evidence of specific incentives targeted at sales agents to motivate ethical sales practice.

**Internal control framework meets some Index criteria.** Gilead's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, involving both internal and external resources, that also applies to third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

**Below average transparency regarding access-related practices.** Gilead publicly discloses its policy positions on access-related topics. For example, it published its position on fair drug pricing, patient access to treatment and intellectual property. It does not have a policy prohibiting political contributions in countries in scope, but reports that no such contributions occurred during the period of analysis. It discloses its membership of relevant organisations but not whether it provides financial support. Further, it does not disclose its policies for responsible engagement, nor does it publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

### RESEARCH & DEVELOPMENT

RANK 18 SCORE 1.43

PROJECTS: 22 IN CLINICAL DEVELOPMENT: 18

**Commits to R&D to meet public health needs.** Gilead has made a specific commitment to R&D for diseases and countries in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on disease burden in low- and middle-income countries. It lacks time-bound strategies for completing R&D projects for diseases in scope. Gilead has one of the smallest pipelines in the Index with 22 projects. For diseases in scope where priorities exist, Gilead is active in eight projects; five of these target priority R&D gaps.

**Access provisions in place for 33% (5/15) of late-stage candidates.** Gilead has a general process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for HIV/AIDS and viral hepatitis B and C. Mainly, Gilead develops access plans for R&D projects in Phase III of clinical development that have clear timelines and processes in place. To date, Gilead has project-specific access provisions in place for

five of its late-stage R&D projects. All five are being conducted in-house.

**No policy for post-trial access.** Gilead does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Additionally, it does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 2 SCORE 3.18

PRODUCTS: 18

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 17

**Commits publicly to equitable pricing and reports a commitment to file to register new products in scope.** Gilead commits to filing its newest products for registration in countries in scope within one year of first market approval, where possible. It also publicly commits to implementing inter-country equitable pricing strategies for the majority of its products for diseases in scope. However, this does not explicitly apply to future products. Its public commitments also apply to intra-country equitable pricing strategies.

**Some new products in scope filed for registration in the majority of priority countries.** Although Gilead commits to filing its newest products for registration in countries in scope within one year of first market approval, it has filed 10% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it publicly shares detailed registration information for almost all of its products.

**94% of products have equitable pricing strategies targeting priority countries.** Gilead's overall performance is strong compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 94% of its products for diseases in scope. These strategies apply to all priority countries. All of the strategies apply to both inter- and intra-country pricing strategies; these take into account an average of four socioeconomic factors. Gilead also applies equitable pricing strategies to 17 additional products informed by a public health rationale.

**Globally consistent recall guidelines for countries in scope but no processes to track products.** Gilead has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

## PATENTS & LICENSING

RANK 3 SCORE 2.75

**Publicly discloses some information on patent statuses.** Gilead discloses the patent status of its products for HIV/AIDS and hepatitis C through its voluntary licensing agreements.

**Uses licensing to enable generic supply.** Gilead leads in this area. The company has non-exclusive voluntary licensing agreements in place for ten compounds (for diseases in scope). Its broadest licence, for bicitgravir, encompasses 91 countries including 61 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

**Shares some IP assets with 3<sup>rd</sup>-party researchers.** Compared to its peers, Gilead shares some IP assets with third-party researchers developing products for diseases in scope. This includes five shared with research institutions, such as the Bill & Melinda Gates Foundation. The assets shared include molecule libraries, data and performing assays for drug discovery.

**No public commitment not to enforce patents in countries in scope.** Gilead does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

## CAPACITY BUILDING

RANK 13 SCORE 1.55

**Eight initiatives included for evaluation.** Gilead has eight capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Gilead submitted 14.

**Focused on strengthening health systems.** Gilead has initiatives which meet inclusion criteria in three areas of capacity building: manufacturing, R&D, and health system strengthening. Most of these initiatives are focused on health system strengthening with a disease focus on HIV/AIDS and viral hepatitis (B and C).

**Two initiatives meet all applicable good practice standards:**

-Gilead Technology Transfers

-Test-and-Treat Demonstration Project

Gilead's remaining included initiatives have goals in place, but fall short on monitoring their progress and outcomes.

**Does not provide evidence of reporting substandard or falsified medicines to relevant authorities.** Gilead has a policy for the prevention and handling of counterfeit medicines. However, it does not provide evidence that it systematically reports cases of substandard or falsified medicines to relevant authorities and/or WHO Rapid Alert.

## PRODUCT DONATIONS

RANK 11 SCORE 2.87

STRUCTURED DONATION PROGRAMMES: 3

**Responds to emergencies and humanitarian crises.** Gilead donated medicines on the request of relief agencies. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it has systems in place to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

**Three donation programmes covering diseases and countries in scope.** Gilead programmes are focused on neglected tropical diseases (NTDs) and communicable diseases. All three programmes are carried out in partnership with partners such as WHO, AHF-Uganda Cares and Jhpiego. Its NTD programme for visceral leishmaniasis supplies amphotericin B (AmBisome®) in six endemic countries and has been ongoing since 1992. Since 2011, Gilead reports donating more than 800,000 total vials of amphotericin b (AmBisome®).

**No transition plans in place.** Gilead does not provide evidence that it considers long-term access to donated products, once a programme ends through, for example transition planning.

## BEST PRACTICES

**Widest use of non-exclusive voluntary licensing**

GLOBAL

Gilead licenses its entire on-patent portfolio of products for diseases in scope to speed the entry of generics into market.

**Full transparency on where products are registered**

GLOBAL

Only company to publish full details of the registration status of its products. A full list is available on company website.