

RANK	SCORE
14	2.84
14 (2021)	

Gilead Sciences

Stock exchange: NASDAQ • Ticker: GILD • HQ: Forster City, California, United States • Employees: 14,000+

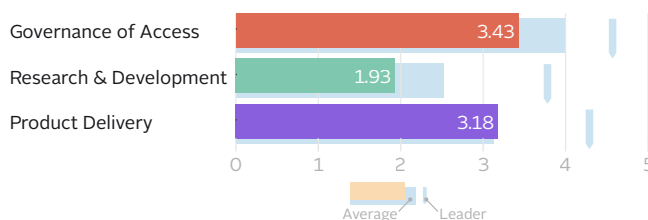
PERFORMANCE IN THE 2022 INDEX

14th place. Gilead has an average overall performance. The company performs well in access strategies for its products on the market, but for R&D it has few access plans in place. Gilead engages widely in non-exclusive voluntary licencing but has a comparatively poor performance in capacity building and aspects of governance of access.

Governance of Access: 15th place. Gilead performs below average in this area. It has an access-to-medicine strategy, although it is not fully integrated into the overall corporate strategy. There is evidence of access-related incentives for its senior executives and CEO, but it lacks evidence of some compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, namely a fraud-specific risk assessment and a continuous system to monitor activities.

Research & Development: 15th place. Gilead performs below average in this area. It has a structured access planning framework but does not apply this to all its late-stage candidates. It has an average performance in R&D capacity building.

How score was achieved



Product Delivery: 12th place. Gilead shows an average performance in this area. The company has access strategies in place for all products assessed in all country income classifications. Gilead leads for engagement in non-exclusive voluntary licencing, with the highest number of licencing agreements of all companies in scope but has comparatively poor performance in health systems strengthening and supply chain capacity building.

OPPORTUNITIES FOR GILEAD

Implement robust framework to mitigate non-compliance. Gilead has country risk-based assessments, third-party monitoring and auditing in place. It can strengthen these processes to mitigate the risk of non-compliant or corrupt activities occurring in countries in scope of the Index by incorporating additional control mechanisms into its operations, such as a continuous system to monitor activities and fraud-specific risk assessments.

Ensure all late-stage R&D projects have comprehensive access plans. Gilead developed access plans for 24% of late-stage projects. The company can develop access plans for all late-stage R&D projects, particularly projects targeting HIV/AIDS and hepatitis B. For example, it can improve the quality of access plans for lenacapavir (Sunlenca®), a long-acting inhibitor for treatment and prevention of HIV, by including additional components such as registration preparation, equitable pricing and/or non-exclusive voluntary licencing.

Expand registration filings of HIV products. Gilead has filed bictegravir/emtricitabine/tenofovir alafenamide (Biktaryv®) in one of the ten countries with the highest burden of HIV. It can take steps to file its HIV products for registration in more high-burden countries, such as Mozambique, Namibia and the Central African Republic.

Extend public commitments to donation programme for visceral leishmaniasis (VL). Gilead has a long-term donation programme that aims to eliminate VL in endemic countries since 2011 in partnership with WHO by donating liposomal amphotericin B (AmBisome®). Gilead has extended its public commitment until 2025. The company can publicly commit to extending the duration of its donation programme until VL is eliminated in endemic countries. The company can also expand the donation programme to more countries where VL is endemic such as Brazil and Somalia.

CHANGES SINCE THE 2021 INDEX

- Established a partnership with Boston University to train its Global Patient Solutions employees and cross-functional partners within Gilead on monitoring and evaluation best practices.
- Joined an initiative with the Partnership for Health Advancement in Vietnam (HAIVN) to address barriers that limit viral hepatitis diagnosis and care at primary healthcare facilities in Vietnam and the Philippines.
- Opened a Paediatric Drug Development Centre of Excellence, focused on developing new paediatric formulations for its portfolio of medicines.
- Announced USD 24 million in grants to help reduce health disparities, improve access to quality healthcare, advance medical education and support local communities most impacted by the HIV epidemic and COVID-19 pandemic. The Zeroing In: Ending the HIV/AIDS Epidemic programme, will support 116 organisations in 41 countries.
- Provided funds to support a global non-profit, FIND, in its project to help eliminate hepatitis C virus (HCV) among people incarcerated in India.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

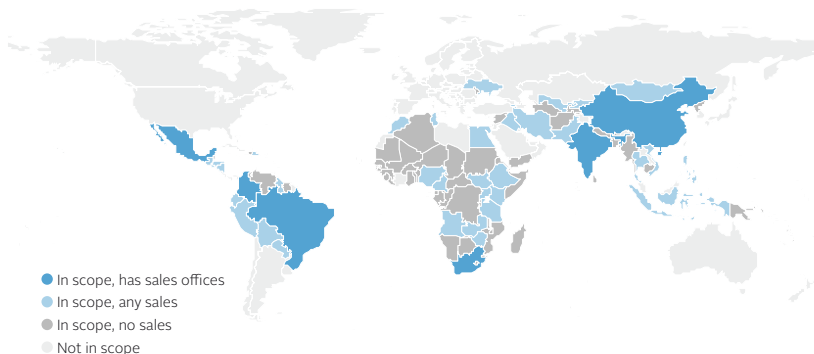
Business segments: Pharmaceutical
Therapeutic areas: Fibrotic diseases, inflammatory diseases, oncology and viral diseases.
Product categories: Innovative medicines.
M&A news: Gilead acquired MYR GmbH in March 2021 for USD 1.45 billion.

Gilead's products are sold in 41 out of 108 countries in scope of the Index.** Gilead has sales offices in 6 countries, and sells via suppliers and/or pooled procurement in an additional 35 countries.

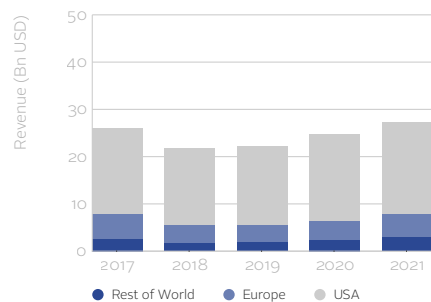
Revenue by segment (2021) – in USD

Pharmaceutical	27.31 bn
Total	27.31 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

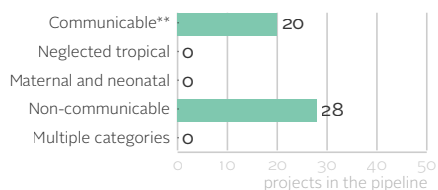
PIPELINE for diseases in scope

Gilead has a total of 48 R&D projects in scope with 17 of these projects targeting a priority disease. The other 31 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (11 projects). Of the projects targeting other diseases in scope, the focus is on oncology (27). Seventeen R&D projects are in late-stage development that target either a priority disease (12) or address a public health need in LMICs (5).* Evidence of access planning was reported for 24% of these projects: four targeting a priority disease and none addressing a public health need in LMICs.

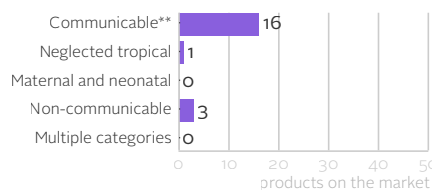
PORTFOLIO as selected for analysis by the Index

Gilead has 20 medicines in scope, 16 of which are on patent. 40% of these medicines (8) are on the WHO EML. The off-patent medicines target mainly communicable diseases, such as HIV/AIDS, hepatitis B as well as neglected tropical diseases such as leishmaniasis. One other product targets cardiovascular diseases. The on-patent medicines mainly target viral infections: HIV/AIDS (8), hepatitis B (1), hepatitis C (4) and coronaviral diseases (1). Two medicines target cancer.

48 projects in the pipeline



20 products as selected for analysis by the Index†



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	4	1	1	9	2	0	17
Addresses needs of LMICs*			1	3	2	0	0	6
Other projects in scope			9	6	8	2	0	25

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	5	11			16
off patent	3	1			4
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other†				0	0

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
 †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
 ‡Other includes vector control products.

Gilead Sciences

GOVERNANCE OF ACCESS

RANK 15

SCORE 3.43

Has an access-to-medicine strategy with measurable objectives. Gilead has an average performance. Its strategy is not fully integrated within the overall corporate strategy, but it does have a business rationale. The access strategy is based on partnerships, and the company sees access as part of its corporate values. It covers some of the therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Nominating and Corporate Governance Committee overseeing pricing and access issues.

Provides evidence of financial access-related incentives at the executive level. Gilead performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine. The CEO also has incentives, linked to its performance in expanding access to HCV products.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Gilead performs average in transparency of access activities. It publicly discloses its commitments, measurable goals, objectives and targets for improving access in countries in scope of the Index. It shares information on the outcomes of only a subset of its

access initiatives, including for HCV and HIV/AIDS and its partnership with Boston University to evaluate its voluntary licensing program, although it does so in a centralised manner within its Year in Review 2021 Report.

Performs above average in responsible promotional practices. Gilead discloses to the Index, but not publicly, whether sales agents are incentivised solely on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for sales agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities) except as required by law, but does have a policy for limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Gilead has an average performance, demonstrating evidence of some components looked for by the Index: audits (both internal and external, covering third parties and in all countries where it operates), country risk-based assessments and formal processes to ensure third-party compliance with

company standards. It does not, however, disclose to the Index whether it has a continuous system to monitor activities, or a fraud-specific risk assessment. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Gilead does not publicly share any support of the Doha Declaration on TRIPS and Public Health. It understands that TRIPS flexibilities, such as compulsory licensing, may play a role in responding to national public health emergencies in the absence of voluntary licensing, but it should only be used by governments as a last resort when all other options have been exhausted. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Gilead, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 15

SCORE 1.93

Access planning processes encompass all projects in the pipeline. Gilead has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Gilead begins developing access plans for R&D projects in Phase II/III of clinical development.

An average-sized priority R&D pipeline compared to peers, with access plans in place for (33%) 4/12 of the late-stage candidates. Gilead has 17 projects, including 12 late-stage candidates in its pipeline that target a priority product gap. These projects focus mainly on HIV/AIDS, hepatitis B and COVID-19. Of Gilead's 12 late-stage candidates targeting a priority product gap, four have evidence of an access plan in place. In these

plans, the availability and affordability of projects in development are considered.

Some projects address a public health need in LMICs.* In this analysis, Gilead has five late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules. Most target cancer. Gilead did not disclose evidence of access plans for any of the five late-stage projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Gilead does not disclose disaggregated R&D investment data

to global health organisations.

Two of the three R&D capacity building initiatives included meet all Good Practice Standards. Gilead's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all Good Practice Standards for this indicator. Notably, Gilead's Public Health Award: Viral Hepatitis Program, provides a grant to support early-stage research scientists in countries within the scope of the Index. This enables applicants to develop innovative strategies for the prevention, care and treatment of viral hepatitis.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 12

SCORE 3.18

No public commitment not to enforce patents in countries in scope. Gilead does not have a public commitment to not file nor enforce patents in low- to middle-income countries.

Publicly discloses information on patent status. Like most of its peers, Gilead discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Gilead discloses patent information such as filing date, grant number, grant date and jurisdiction.

Is an average-performing company in terms of sharing intellectual property (IP) assets with third-party researchers. Gilead engaged in one new IP-sharing agreement with third-party research institutions or drug discovery initiatives established during the current analysis period that meets all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current Index cycle and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. Gilead is the company with the highest number of licensing agreements. It has non-exclusive voluntary licensing agreements in place for 11 marketed compounds (for diseases in scope). Its broadest licences, for sofosbuvir (Sovaldi®), sofosbuvir/ledipasvir (Harvoni®), sofosbuvir/velpatasvir (Epclusa®), sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) encompass 92 countries within the scope of the Index, including 67 middle income countries. Gilead's recent license for remdesivir (Veklury®) includes nine sublicensees and covers 90 countries in scope, including 67 middle income countries.

Filed to register new products in six countries in scope on average. Gilead did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely filed is tenofovir alafenamide (Vemlidy®), indicated for viral hepatitis (B and C), filed in 35 countries in scope of the Index, including three of the top 10 high burden countries (Myanmar, Egypt and Cambodia). Emtricitabine/tenofovir alafenamide (Descovy®), for HIV/AIDS, has been filed for registration in seven of the top 10 high burden countries (Botswana, Central African Republic, Mozambique, Namibia, South Africa, Zambia and Zimbabwe).

Has access strategies for its supranationally procured product in scope for this analysis. Gilead has an average performance in securing access for the product procured supranationally. The company demonstrates strategies in countries eligible for supply from procurers and also in at least one non-eligible country. For example, Gilead's price for amphotericin b liposome (AmBisome®) is USD 16.25, and it is the same in all 116 countries covered by the company's volun-

tary licensing agreements for HIV/AIDS products. In addition, Gilead has a long-term donation partnership with WHO. In Mexico, a non-eligible country to benefit from the procurement agreement, Gilead does not apply the same price offered via such agreement, but it implements a tiered pricing policy. Evidence of additional access strategies is not provided but the company shares patient reach data.

Has access strategies for its healthcare practitioner-administered product for countries in the scope of the analysis. Gilead performs above average in this area. It provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC) for the product assessed. For example, Gilead has a voluntary licensing programme for remdesivir (Veklury®), which includes a technology transfer to generic manufacturers developing this product and a waiver of royalties on COVID-19 therapies for use during the pandemic. The company reported that these efforts resulted in a four-fold increase in production during the peak of the COVID-19 surge in India, from 3 million vials to 13 million vials. In addition, Gilead donated vials to meet the patients' immediate needs in India. Evidence of patient reach in the three country examples is provided.

Has access strategies for all its self-administered products for countries in scope for this analysis. Gilead leads in this area. Examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC) are provided for all its products assessed. The company makes efforts to reach additional patients through flat pricing strategies in LICs and non-exclusive voluntary licensing agreements. Evidence of tiered pricing policies considering public payers' ability to pay is available, such as in the Dominican Republic for sofosbuvir/velpatasvir (Epclusa®), where the company reached 3,078 patients.

One of the four manufacturing capacity building initiatives included meets all Good Practice Standards. Gilead's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In the initiative that meets all GPS, Gilead builds manufacturing capacity of its licensees in LMICs by initiating technology transfers for generic HIV/AIDS and hepatitis C treatments ahead of regulatory approval.

One supply chain capacity building initiative was included for analysis but does not meet all Good Practice Standards. Gilead's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. The Gilead GPS Dashboard training initiative teaches licensees

how to access several data sources to ensure continuous supply in multiple countries.

Two of the five health systems strengthening initiatives included meets all Good Practice Standards. Gilead's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all GPS than what is average for this indicator. For example, Gilead is partnering with the Vatican and others to reach people living with HIV/AIDS in the rural Shinyanga and Simiyu regions of Tanzania and quickly connect them to care. The programme aims to enable screening of 300,000 people and provide treatment for all those diagnosed. This initiative meets all GPS.

Has engaged in piloting one inclusive business model and has scaled up two existing inclusive business models during the current analysis period. Gilead performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Gilead continues to support the M-TIBA mobile wallets programme, which provides access to better healthcare by connecting people directly to healthcare payers and clinics through a health wallet on their mobile phones.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Gilead is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, and manages a buffer stock of relevant products. However, there is no evidence to show that the company is involved in supply chain capacity building initiatives.

Does not have a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index. Gilead does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to the relevant health authorities.

Donates in response to expressed need and monitors delivery. Gilead has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Since 2011, Gilead publicly committed itself to contribute to the elimination of visceral leishmaniasis by donating amphotericin B liposome (AmBisome™) in six countries in scope of the Index until 2025.