Performance in the 2021 Index

14th place. Gilead has an average overall performance. It performs strongly in financial access-related incentives but poorly in responsible promotional practices. The company has a small R&D pipeline with a few access plans, yet it strongly engages in licences to enable generic supply.

Governance of Access: 12th place. Gilead performs below average in this area. The company offers access-related incentives at the executive level, but discloses limited information in the area of responsible promotional practices.

Research & Development: 13th place. Gilead has an average performance in this area. The company has a structured process in place for access planning during R&D for some of its products but does not publicly disclose a post-trial access policy. It has a small-sized priority R&D portfolio compared to peers with one product covered by an access plan.

Product Delivery: 13th place. Gilead has an average performance in this area. The company filed to register some of its products in the majority of the high-burden countries, yet it implements strategies to improve access to only some of its products in some markets. The company performs strongly in licensing, with licences in place for ten marketed compounds.

Opportunities for Gilead

Manage the risk of misconduct and non-compliance in LMICs. Gilead can review sales incentive structures to adopt a balanced scorecard approach consistently, thus not solely promoting sales volumes as a performance target for its sales agents in LMICs. Furthermore, it can strengthen processes to mitigate the risk of non-compliant or corrupt activities occurring in Index countries by incorporating additional control mechanisms into its operations.

Expand registration filings of HIV products. Gilead can take steps to file its HIV products for registration in more high-burden countries, including products for which Gilead has entered into non-exclusive voluntary licensing agreements. The company has filed emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey®) in none of the top 10 high-burden countries, Biktarvy® and Genvoya® in only one of the top 10 high-burden countries and Descovy® in four out of those 10 countries. Additional countries the company can consider include Lesotho and Zimbabwe.

Apply access planning process to all R&D projects. Gilead has a structured process in place for access planning for R&D projects in Phase II for HIV, viral hepatitis and visceral leishmaniasis. It has specific access plans in place for some late-stage projects. The company can expand its access plans to all late-stage R&D projects, such as for lenacapavir, a long-acting HIV-1 capsid inhibitor and projects targeting RSV and cancer. Furthermore, it can ensure that such products will be registered in countries where clinical trials take place and ensure affordable access to these products.

Change since the 2018 Index

- Received WHO prequalification for sofosbuvir/velpatasvir (Epclusa®), the first treatment for hepatitis C, in February 2019.
- Joined Pat-INFORMED in 2018.
- Issued licences for remdesivir (Veklury®); a treatment for COVID-19, which received Emergency Use Authorisation by the FDA during the period of analysis, covering 127 countries, including technology transfer.
- Joined the COVID-19 Therapeutics Accelerator.

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. For the 2021 Index, Gilead declined to submit data to the Access to Medicine Index.

The term LMIC is used to denote all low- and middle-income countries in the 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.

***Remdesivir (Veklury®) was not included in the product portfolio, FDA approved it for the treatment of COVID-19 after period of analysis (October 2019).
SALES AND OPERATIONS

Business segment: Innovative medicines

Therapeutic areas: Viral Diseases; Inflammatory Diseases; Oncology; Fibrotic Diseases

Product categories: Innovative medicines

M&A news: Acquired Forty Seven (oncology) for USD 4.9 billion, Immunomedics (oncology) for USD 20 billion and MYR GmbH (chronic hepatitis delta virus) for USD 1.4 billion in 2020.

Gilead’s products are sold in 32* out of 106 countries in scope. Gilead has sales offices in 5 countries and sells products via suppliers or pooled procurement in 27* countries.

Revenue by segment (2019) – USD

Innovative medicines 22.449 bn

Total 22.449 bn

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Gilead has a total of 21 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 9 projects. Remarkably, these 9 priority projects make up almost half of Gilead’s R&D projects. The other 12 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (5 projects). Of the projects targeting other diseases in scope, the focus is on oncology (9). 9 R&D projects are in late-stage development that target either a priority disease (6) or address a public health need in LMICs (3).* Evidence of access planning was reported for 11% of these projects: 1 targeting a priority disease and none addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

Gilead has 19 medicines in scope, 15 of which are on patent. 47% of these medicines (9) are on WHO’s EML. The off-patent medicines target mainly communicable diseases, such as HIV, hepatitis B as well as neglected tropical diseases such as leishmaniasis. One other product targets cardiovascular diseases. The on-patent medicines target viral infections: HIV (9), hepatitis B (1) and hepatitis C (4). One product targets cancer. Access strategies were analysed for 7 products on Gilead’s portfolio – supranationally procured (4) or nationally procured self-administered products (3).

21 projects in the pipeline

Breakdown of projects*

<table>
<thead>
<tr>
<th>Category</th>
<th>Projects in the pipeline</th>
<th>Products on the market</th>
</tr>
</thead>
<tbody>
<tr>
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<td>16</td>
</tr>
<tr>
<td>Neglected tropical</td>
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<td>0</td>
</tr>
<tr>
<td>Maternal and neonatal</td>
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<td>0</td>
</tr>
<tr>
<td>Non-communicable</td>
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<td>2</td>
</tr>
<tr>
<td>Multiple categories</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*32 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, 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.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

† Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

††Projects in the discovery phases and/or other drug development phases were not included in this breakdown.
**Gilead Sciences Inc**

### GOVERNANCE OF ACCESS

**RANK 12**  **SCORE 2.89**

Has an access-to-medicine strategy with measurable objectives and a business rationale. Gilead has an average performance in this area. It has an access strategy based on partnerships and sees access as part of its corporate values. The strategy 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 well here. The CEO has incentives, linked to its performance in expanding access to HCV products. The company does not disclose, however, whether senior executives and in-country managers are also incentivised toward access goals.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Gilead performs well in transparency regarding access activities. It publicly discloses its commitments, measurable goals, and targets for improving access in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example through the IPMA Global Health Progress platform.

Performs comparatively poorly in responsible promotional practices. Gilead's sales agents are solely incentivised on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It has an anti-bribery and anti-corruption policy, but does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g., payments for attending events or promotional activities).

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Gilead performs below average, with evidence of some of the components looked for by the Index audits (both internal and external, covering third parties and in all countries where it operates) 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, fraud-specific risk assessment or country risk-based assessment.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Gilead does not publicly share any support of or statement on the Doha Declaration on TRIPS and Public Health. There is no evidence of a policy to dissent from industry association positions.

### RESEARCH & DEVELOPMENT

**RANK 13**  **SCORE 1.71**

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

A small-sized priority R&D pipeline compared to peers, with access plans in place for 17% of the late-stage candidates. Gilead has nine projects, including six late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on HIV/AIDS. Of Gilead's six late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This plan for the COVID-19 product remdesivir includes a non-exclusive voluntary licensing agreement with several generic medicine manufacturers, a technology transfer of the Gilead manufacturing process. The licences are royalty-free until the WHO declares the end of the COVID-19 public health emergency of international concern or until a pharmaceutical product other than remdesivir or a vaccine is approved to treat or prevent COVID-19. The regulatory approval status of remdesivir varies by country.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for the late-stage projects. In this analysis, Gilead has three 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.

No public disclosure of post-trial access policy. Gilead does not have a publicly available policy for ensuring post-trial access to treatments for clinical trial participants nor did it disclose such a policy to the Index.

Two R&D capacity building initiatives included for evaluation. Gilead performs below average in this indicator, with two R&D capacity building initiatives included for analysis. Gilead's initiatives were identified for selection based on publicly available information. The initiatives were also included in the 2018 Index.

### PRODUCT DELIVERY

**RANK 13**  **SCORE 2.50**

Lacks a public commitment not to enforce patents in countries in scope. Gilead does not have a public policy that sets out its approach to filing or enforcing patents in low- and middle-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Gilead discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

One IP asset shared with third-party researchers. During the period of analysis Gilead newly shared one IP asset with third-party researchers developing products for diseases in scope. It shares this asset with the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. The asset shared is molecule libraries.

Uses licensing to enable generic supply. Gilead is the company with the highest number of licensing agreements. The company has non-exclusive voluntary licensing agreements in place for ten marketed compounds (for diseases in scope). Its broadest licences, for bicitravir, cobicitabiv, emtricitabine, tenofovir alafenamide and tenofovir disoproxil fumarate encompass 91 countries in scope, including 64 middle-income countries in scope. It recently agreed on a licence for remdesivir (Veklury®), a treatment for COVID-19* (it received Emergency Use Authorisation by the FDA during period of analysis). It has not issued any non-assert declarations for products in scope.

Filed to register some new products in the majority of high burden countries. Gilead has filed 10% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For instance, sofosbuvir/ledipasvir (Harvoni®) for viral hepatitis (B and C) has been filed for registration/registered in five high burden countries in scope, including Egypt.

Has access strategies for all supranationally procured products in scope for this analysis. Gilead per-

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*Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

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forms average in securing access for products procured supranationally. For the four products assessed in this category, the company demonstrated strategies both in countries eligible for supply from such procurers and also in at least one non-eligible country. However, no patient reach has been demonstrated for any of the products. For example, the company has equitable strategies, donations and licences for the HIV/AIDS medicine emtricitabine/tenofovir disoproxil fumurate (Truvada®) for non-eligible Global Fund countries.

No healthcare practitioner-administered products.
Gilead has no products eligible for scoring in this indicator.

Has access strategies for some of its self-administered products for countries in scope for this analysis.
Gilead performs average in this area. Examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) was found publicly for two of the three products assessed. The company makes efforts to reach additional patients through equitable pricing strategies and licensing. For example, in LICs, it uses flat pricing and non-exclusive voluntary licensing to increase access to hepatitis medicines sofosbuvir (Sovaldi®) and sofosbuvir/ledipasvir (Harvoni®). Information which demonstrates patient reach through these approaches is not available.

One manufacturing capacity building initiative meets all Good Practice Standards. Gilead performs below average in this indicator, with one manufacturing capacity building initiative included for analysis and meeting all Good Practice Standards. Gilead’s initiative, which includes the technology transfers to manufacturers that hold a product licence through the MPP, was identified for selection based on publicly available information. The initiative was also included in the 2018 Index.

No supply chain capacity building initiatives included for evaluation. Gilead has no initiatives included for analysis aimed at building supply chain capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building supply chain capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

One health system strengthening initiative meets all Good Practice Standards. Gilead performs below average in this indicator, with one health system strengthening initiative included for analysis and meeting all Good Practice Standards. Gilead’s initiative, which includes the Test-and-Treat Demonstration Project in Tanzania, was identified for selection based on publicly available information. The initiative aims to reach people living with HIV and provide them with care. To date, the initiative has screened 300,000 people and provided treatment to an estimate of 20,000 diagnosed people. The initiative was also included in the 2018 Index.

Has engaged in the development and implementation of a new inclusive business model. Gilead improved performance since 2018 when it comes to implement-