

RANK	SCORE
<b>20</b>	<b>1.79</b>
18 (2021)*	

# Eli Lilly & Co

Stock exchange: NYSE • Ticker: LLY • HQ: Indianapolis, Indiana, United States • Employees: ~35,000

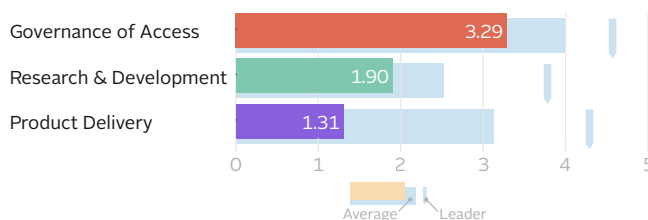
## PERFORMANCE IN THE 2022 INDEX

20<sup>th</sup> place. Eli Lilly is in the lower ranks across all Technical Areas. The company has a small priority R&D pipeline and has no structured process for access planning during R&D. Its Governance of Access policies are comparatively poor, with no publicly-available evidence found of responsible promotional practices and top-level incentivisation to achieve access-related goals.

**Governance of Access:** 19<sup>th</sup> place. Eli Lilly performs poorly in this area. It has an access-to-medicine strategy centred around its Lilly 30x30 programme and publicly discloses outcomes of its access-to-medicine initiatives, but it discloses little information related to responsible promotional practices and lacks evidence of access-related incentives for its senior executives and in-country and regional managers as well as some compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

**Research & Development:** 16<sup>th</sup> place. Eli Lilly performs below average in this area. Eli Lilly does not have an access planning

How score was achieved



framework in place for R&D projects. It has a small-sized priority pipeline compared its peers, with plans for registration for most late-stage pipeline candidates. Eli Lilly does not participate in R&D capacity building.

**Product Delivery:** 20<sup>th</sup> place. Eli Lilly performs poorly in this area. It does not disclose, neither publicly nor to the Index, access strategies for its products nor examples of manufacturing and supply chain capacity building initiatives. However, the Index identified several high-quality health systems strengthening initiatives in which the company participates. The company has a non-exclusive voluntary licensing agreement in place for one compound.

## OPPORTUNITIES FOR ELI LILLY

**Review sales incentive structure.** Eli Lilly has an access-to-medicine strategy integrated within its overall corporate strategy and incentivises its CEO to achieve access-to-medicine goals. It can decouple sales incentives for its sales agents from sales volume in countries in scope of the Index.

**Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans.** Eli Lilly has access plans in place for 76% of late-stage R&D projects. The company can develop a structured access planning process in order to develop access plans for all late-stage R&D projects. For example, Eli Lilly can expand access plans for tirzepatide for type 2 diabetes, and new cancer treatments such as sintilimab, to include further access commitments beyond registration of the product in countries where it is conducting clinical trials.

**Expand registration of medicines.** Eli Lilly did not disclose any evidence of new data regarding registration filings. The company can expand registration of new products such as selpercatinib (Retevmo®/Retsevmo®), indicated for thyroid and lung cancer, and analogue insulins such as insulin lispro (Lyumjev™) and insulin glargine (Basaglar®).

**Expand access strategies to patented cancer products.** Eli Lilly can expand access to its patented cancer products, such as abemaciclib (Verzenio®) for breast cancer, by applying different access strategies, such as equitable pricing. Additionally, it can engage in non-exclusive voluntary licensing for this product to enable generic supply, as it did for baricitinib (Olumiant®) for the treatment of COVID-19, in India.

## CHANGES SINCE THE 2021 INDEX

- Extended support in 2021 to the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act.
- Disclosed progress in patient reach through the Lilly 30x30 Programme, reaching 11.6 million people in 2021 out of the 30 million 2030 goal.
- Issued a royalty-free, non-exclusive voluntary license for baricitinib (a drug repurposed to treat COVID-19) to three Indian drug makers.
- Invested USD 100 million into the newly launched Antimicrobial Resistance (AMR) Action Fund.
- Expanded the initiative in partnership with Life for a Child to provide free immediate care as well as build sustainable diabetes care models for vulnerable populations. Starting in February 2021, the partners plan to expand access to care for youth with diabetes from approximately 23,000 in 2020 to approximately 150,000 in 65 countries over the next 10 years.
- Committed USD 14.4 million in a new partnership with UNICEF to help improve health outcomes for 10 million children and adolescents living with chronic, non-communicable diseases (NCDs) through 2025.

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. For

the 2022 Index, Eli Lilly declined to submit data to the Access to Medicine Index. 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.

\*In the 2021 Index, dense ranking was used. In the 2022 Index, standard competitive ranking is used. Therefore, a direct comparison with Eli Lilly's previous rank is not possible.

### SALES AND OPERATIONS

**Business segments:** Human pharmaceutical products.

**Therapeutic areas:** Diabetes, immunology, neuroscience, oncology and other therapies.

**Product categories:** Innovative medicines.

**M&A news:** Eli Lilly acquired Prevail

Therapeutics Inc. in January 2021 for USD 747.4 million. Eli Lilly also acquired Protomer Technologies in July 2021 for USD 1 billion.

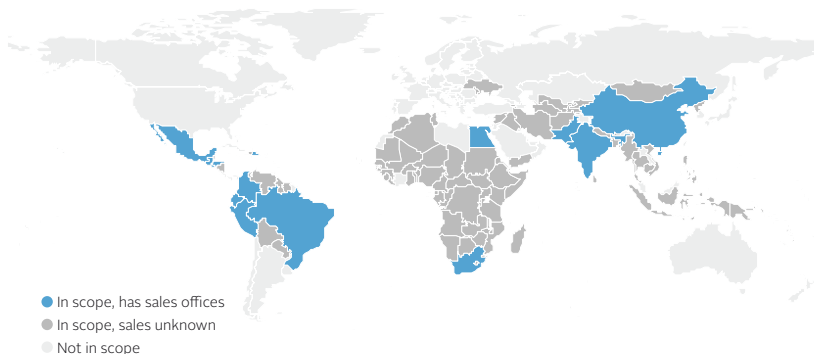
Eli Lilly's products are sold in 72\* out of 108 countries in scope of the Index. Eli Lilly has sales offices in 14 countries and sells via suppliers and/or pooled procurement in 68\* countries.

\*In 2016, Eli Lilly reported sales in 72 countries.

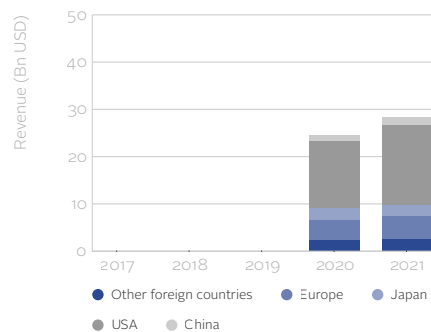
#### Revenue by segment (2021) – in USD

Human pharmaceutical products	28,32 bn
Total	28,32 bn

#### Sales in countries in scope



#### Sales by geographic region



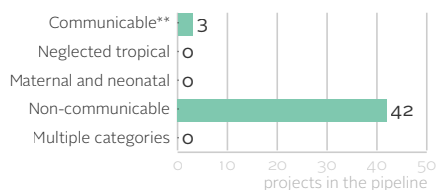
### SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

#### PIPELINE for diseases in scope

Eli Lilly has a total of 45 R&D projects in scope with three of these projects targeting priority diseases. The other 42 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on COVID-19 (three projects). Of the projects targeting other diseases, the focus is on diabetes mellitus (13), oncology (12) and ischaemic heart disease (7).

Seventeen R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (14).<sup>\*</sup> Evidence of access planning was in place for 76% of these projects: three targeting a priority disease and ten addressing a public health need in LMICs.

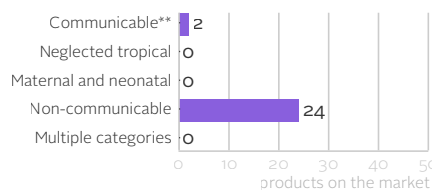
#### 45 projects in the pipeline



#### PORTFOLIO as selected for analysis by the Index

Eli Lilly has 26 medicines in scope, 18 of which are on patent. 19% of these medicines are on the WHO EML (5). The off-patent medicines target non-communicable diseases (NCDs) such as diabetes (5), cancer (1) and unipolar depressive disorders (1). The on-patent medicines target NCDs such as diabetes (9), cancer (4) cardiovascular disease (1) and migraine (2).

#### 26 products as selected for analysis by the Index<sup>†</sup>



#### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	0	0	0	3	0	3
Addresses needs of LMICs*			5	4	7	3	0	19
Other projects in scope			15	3	3	2	0	23

#### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	1	17			18
off patent	4	4			8
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other <sup>†</sup>				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).  
<sup>†</sup>Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.  
<sup>‡</sup>Other includes vector control products.

# Eli Lilly & Co

## GOVERNANCE OF ACCESS

RANK 19

SCORE 3.29

**Has an access-to-medicine strategy with measurable objectives, integrated with its corporate strategy.** Eli Lilly performs well. It has an access-to-medicine strategy, which covers some of the therapeutic areas in which the company is involved. The strategy is centred around the Lilly 30x30 programme, which focuses on diseases that disproportionately affect people in resource-limited settings. The highest responsibility lies indirectly with the board, with a senior executive responsible for access strategies and reporting to the Executive Committee, which is chaired by the CEO.

**Provides evidence of financial access-related incentives at the executive level.** Eli Lilly performs well. The CEO has access-related incentives linked to its ability to drive the 30x30 strategy and ensure progress. Eli Lilly does not disclose, however, whether senior executives and in-country managers are also incentivised toward access goals.

**Publicly disclose outcomes of its access-to-medicine activities.** Eli Lilly performs strongly in transparency of access activities.

It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its Lilly 30x30 Programme in a centralised manner within its ESG report.

**Performs comparatively poorly in responsible promotional practices.** Eli Lilly does not disclose whether sales agents are incentivised on measures other than sales volume. There is evidence that the company sets incentives based on sales targets at the individual level for 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), unless required by local regulations or trade associations.

**Has compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.** Eli Lilly has an average performance, demonstrating evidence of some components looked for by the

Index: a continuous system to monitor activities, audits, formal processes to ensure third-party compliance with company standards and country risk-based assessments in every country or region where there is an Ethics & Compliance officer present. There is no evidence, publicly found or disclosed to the Index, of 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.** Eli Lilly does not publicly share any support of the Doha Declaration on TRIPS and Public Health, but disclosed to the Index that its position aligns with IFPMA. 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, Eli Lilly, like all other member companies in scope of the Index, is by default connected to this activity.

## RESEARCH & DEVELOPMENT

RANK 16

SCORE 1.90

**No structured process for access planning reported.** Eli Lilly does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

**A small-sized priority R&D pipeline compared to peers, with access plans in place for 100% (3/3) late-stage candidates.** Eli Lilly has three late-stage candidates in its pipeline that target a priority product gap. These focus on COVID-19. The company did not disclose any access plans for these late-stage projects. However, evidence of access plans for all three COVID-19 projects was found in the public domain. For example, Eli Lilly has issued royalty-free, non-exclusive voluntary licenses to accelerate and expand the availability of baricitinib (Olumiant®) to treat COVID-19 in India. This plan also considers donations and registration in countries in scope. Eli Lilly considers supply, demand, and equitable

pricing for its bebtelovimab, a monoclonal antibody therapeutic for COVID-19. Through the Bill & Melinda Gates Foundation, Eli Lilly provided doses of bamlanivimab free of charge in Rwanda and Morocco.

**Many projects address a public health need in LMICs,\* with 71% (10/14) of late-stage candidates covered by access plans.** In this analysis, Eli Lilly has 14 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 concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. These projects focus on several diseases including Alzheimer's disease, diabetes mellitus (type 1 and 2), cancer and cardiovascular diseases. The company did not disclose any access plans for the late-stage projects. However, Eli Lilly has a

policy whereby once a product is approved, it commits to registering it in all countries where clinical trials have taken place. Therefore, plans for registration in countries where clinical trials are being carried out apply to 10 of the 14 late-stage projects.

**Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.** Eli Lilly does not disclose disaggregated R&D investment data to global health organisations.

**No R&D capacity building initiatives included for evaluation.** There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Eli Lilly's performance is below average in this area.

\*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 20

SCORE 1.31

**Public commitment not to enforce patents in countries in scope.** Eli Lilly publicly pledges to neither file for nor enforce patents. This commitment, available online in the "2018 UNGC Communication on Progress" report, applies to all Least Developed Countries.

**Publicly discloses information on patent status.** Like most of its peers, Eli Lilly publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Eli Lilly includes information about patents, including filing date, grant number, grant date and jurisdiction.

**Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers.** Eli Lilly 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 not have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

**Uses licensing agreements to enable generic supply.** Eli Lilly has a non-exclusive voluntary licensing agreement in place for one compound, baricitinib (Olumiant®) in India. Details of this agreement are not publicly available.

**No evidence of filing for registration new products in any country in scope on average.** Eli Lilly did not disclose evidence of filing for registration any of its analysed products.

**Eli Lilly is not eligible for assessment of supra-nationally procured products.**

**Has access strategies for one of its healthcare practitioner-administered products in scope of this analysis.** Eli Lilly performs below average in this area. For one of five products assessed in this category, examples of access strategies in LMIC were found publicly. For example, the company has issued royalty-free, non-exclusive voluntary licences to three Indian drug makers, Cipla, Sun Pharmaceuticals and Lupin, to manufacture and distribute baricitinib (Olumiant®) to treat COVID-19. In addition, Eli Lilly has donated 400,000

baricitinib tablets to the Indian government for eligible hospitalised COVID-19 patients in India. On May 4 2021, Eli Lilly announced it would donate doses of baricitinib and bamlanivimab/etesevimab to Direct Relief. This donation would enable the humanitarian organisation to provide COVID-19 therapies at no cost to LMICs most heavily impacted by the pandemic. The number of doses donated was not disclosed.

**No evidence of access strategies for any of its self-administered products in scope for this analysis.** Eli Lilly has not disclosed, neither publicly nor to the Index, access strategies for any of the five products, assessed in this category. Four products in this category are indicated for diabetes mellitus treatment and one product is a cancer treatment.

**No manufacturing capacity building initiatives included for analysis.** There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Eli Lilly's performance is below average in this area.

**No supply chain capacity building initiatives included for analysis.** There is no evidence — in the public domain or disclosed to the Index — of supply chain capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Eli Lilly's performance is below average in this area.

**Two of the four health systems strengthening initiatives included meet all Good Practice Standards.** Eli Lilly's performance is average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, Eli Lilly is a partner in the Africa Health Worker Training Initiative with Living Goods and Last Mile Health which explores novel approaches to training and retaining community health workers. This initiative meets all GPS.

**Has no inclusive business models that meet all inclusion criteria.** There is no evidence that Eli Lilly has engaged in the piloting or scale-up of

any inclusive business models that aim to meet the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Eli Lilly performs below average in this area.

**Shows average performance in terms of ensuring continuous supply of medicines in LMICs.** Eli Lilly has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, manages a buffer stock of relevant products, and produces in-house active pharmaceutical ingredients to prevent shortages. However, there is no evidence that the company is involved in technology transfers to manufacturers in LMICs or supply chain capacity building initiatives that meet the inclusion criteria for evaluation.

**Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index.** Eli Lilly provides evidence of a policy for reporting SF medicines to relevant national health authorities. However, it does not disclose, publicly or to the Index, evidence that it requires reporting to occur within the timeframe of ten days looked for by the Index. Eli Lilly also does not provide evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed.

**Donates in response to expressed need and monitors delivery.** Eli Lilly 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 until they reach the patient.

**Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator.** However, the company is engaged in other structured donation programmes, such as the Life for a Child programme where it donates insulin lispro (Humalog®), an analogue insulin used to treat type 1 diabetes mellitus, in 23 countries since 2009.