PERFORMANCE IN THE 2021 INDEX

18th place. Eli Lilly is in the lower ranks across, with weak performances in all Technical Areas. The company features a comparatively small priority R&D pipeline and has no structured process for access planning during R&D.

Governance of Access: 13th place. Eli Lilly performs below average in this area. The company’s Lilly 30x30 programme is an access-to-medicine strategy that covers some therapeutic areas. Yet, the company performs relatively poorly in responsible promotional practices with sales agents solely incentivised on sales volume targets and with no information publicly available on transfer of values to healthcare professionals in countries in scope.

Research & Development: 19th place. Eli Lilly falls to the lower ranks in R&D. It does not have a structured process for access planning during R&D. Only a few access plans for late-stage R&D projects are identified.

Product Delivery: 18th place. Overall, Eli Lilly performs poorly. It does not disclose, either publicly or to the Index, access strategies for its products and has no manufacturing and supply chain capacity building initiatives, either. It is engaged in three health system strengthening initiatives that meet all Good Practice Standards.

OPPORTUNITIES FOR ELI LILLY

Improve transparency on access-to-medicine activities. Eli Lilly can improve transparency on its access-to-medicine activities by publicly disclosing progress and outcomes of such activities consistently, including through partners’ platforms such as the IFPMA Global Health Progress. This applies to initiatives active during the period of analysis, namely its ongoing Lilly 30x30 programme in LMICs.

Develop an access planning process and access plans for all R&D projects. Eli Lilly can develop a formal access planning process and accordingly develop access plans for all clinical Phase II projects such as its diabetes projects nasal glucagon and tirzepatide (dual GIP and GLP-1 receptor agonist) in late-stage clinical development. Furthermore, Eli Lilly can update and publish a post-trial access policy allowing for continued access to investigational treatments for clinical trial participants and can commit to registering the product in countries where clinical trials take place while ensuring affordability.

Improve access to products on WHO EML. Eli Lilly has three products which are on the 2019 WHO Model List of Essential Medicines (WHO EML), for diabetes. The company can prioritise expanding access to these products by increasing affordability and supply through equitable pricing. The company should take into account the different socio-economic levels and offer tailored pricing for different population segments.

Expand operations and registration of medicines. Eli Lilly’s most widely registered new product, dulaglutide (Trulicity®) for Type 2 diabetes mellitus, is registered in only seven countries in scope. The company now operates in fourteen countries in scope of the Index. It can expand operations to more countries and expand registration of new products such as dulaglutide (Trulicity®).

CHANGE SINCE THE 2018 INDEX

- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Has a new Steering Committee since 2018, overseeing progress on Lilly 30x30 initiative.
- Disclosed a progress in patient reach through the 30x30 efforts.
- Entered into an agreement with the Bill and Melinda Gates Foundation to facilitate access to new therapeutic antibodies in LMICs and released Lilly’s Principles of COVID-19 Antibody Therapy Pricing and Access.
- Joined the COVID-19 Therapeutics Accelerator.
- Partners with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four Pharmaceutical companies on Africa Health Worker Training Initiative.
- Supported its global health partner, AMPATH (the Academic Model Providing Access to Healthcare), with the expansion of its model to two more countries: Ghana and Mexico.

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, Eli Lilly 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.
**SALES AND OPERATIONS**

**Business segment:** Human pharmaceutical products  
**Therapeutic areas:** Diabetes and other endocrinology; Immunology; Neuroscience; Oncology.  
**Product categories:** Innovative medicines.  
**M&A news:** Spun off Elanco (Animal health) in 2019; acquired Loxo Oncology for USD 8 billion in 2019 and Dermira Inc. (immunology) in 2020 for approximately USD 1.1 billion in 2020. Announced the acquisition of Disarm Therapeutics (axonal degeneration) in October 2020, for USD 135 million upfront and up to USD 1.225 billion in potential future milestones.

**Eli Lilly's products are sold in 72* out of 106 countries in scope.** Eli Lilly has sales offices in 14 countries and sells products via suppliers or pooled procurement in 68* countries.

*In 2016, Lilly reported sales in 72 countries.

**Sales in countries in scope**

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

**PIPEDLINE** for diseases and countries in scope  
Eli Lilly has a total of 46 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 6 projects. The other 40 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on tuberculosis (3 projects) and COVID-19 (3). Of the projects targeting other diseases in scope, the focus is on oncology (15) and diabetes mellitus (14).

17 R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (14).

Evidence of access planning was reported in these sections for 6% of these projects: 1 targeting a priority disease but none addressing a public health need in LMICs.

**PORTFOLIO** as selected for analysis by the Index  
Eli Lilly has 23 medicines in scope, 15 of which are on patent. 13% of these medicines are on WHO's EML (3 products). The off-patent medicines target non-communicable diseases (NCDs) such as diabetes (5), cancer (1), cardiovascular diseases and mental health. The on-patent medicines target the NCDs diabetes (9), cancer (4) cardiovascular disease (1) and migraine (1).

Access strategies were analysed for 9 products on Eli Lilly's portfolio—nationally procured HCP-administered (4) and self-administered products (5).

**46 projects in the pipeline**

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable</td>
<td>6</td>
</tr>
<tr>
<td>Neglected tropical</td>
<td>0</td>
</tr>
<tr>
<td>Maternal and neonatal</td>
<td>0</td>
</tr>
<tr>
<td>Non-communicable</td>
<td>40</td>
</tr>
<tr>
<td>Multiple categories</td>
<td>0</td>
</tr>
</tbody>
</table>

**Breakdown of projects**

- Nasal glucagon powder for severe hypoglycaemia in children (aged ≤ 4 years) and adults with diabetes.

- **23 products as selected for analysis by the Index**

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable**</td>
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</tr>
<tr>
<td>Neglected tropical</td>
<td>0</td>
</tr>
<tr>
<td>Maternal and neonatal</td>
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<tr>
<td>Non-communicable</td>
<td>23</td>
</tr>
<tr>
<td>Multiple categories</td>
<td>0</td>
</tr>
</tbody>
</table>

**Access plans**

- **Breakdown of products**

<table>
<thead>
<tr>
<th>Category</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO EML</td>
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</tr>
<tr>
<td>WHO EDL</td>
<td>15</td>
</tr>
<tr>
<td>Non-WHO EML</td>
<td>5</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
</tr>
</tbody>
</table>

- **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.**

- **Who is the pipeline for diseases and countries in scope?**

- **What is the Breakdown of projects?**

- **How many projects are selected for analysis by the Index?**

- **What are the types of products selected for analysis?**

- **What are the access plans for the selected products?**
Eli Lilly & Co

GOVERNANCE OF ACCESS

Rank 13  Score 2.85

Has an access-to-medicine strategy with measurable objectives and a business rationale. Eli Lilly has an average performance. It has an access strategy, centred around the Lilly 30x30 programme, which goes beyond philanthropy. The strategy covers some of the therapeutic areas in which the company is involved, for example some non-communicable diseases (NCDs) including diabetes. While the board oversees access, the highest responsibility lies with the CEO and the executive team. A new Steering Committee oversees progress on Lilly 30x30.

Provides evidence of financial access-related incentives at the executive level. 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.

Does not publicly disclose outcomes of its access-to-medicine activities. Eli Lilly performs below average on transparency regarding access initiatives. It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope, also via the IFPMA Global Health Progress platform, namely with its Lilly 30x30 Programme initiatives. It does not, however, share the outcomes of its individual access activities during the period of analysis, but reports having reached 7.2 million patients in 2019, compared to 2015 through Lilly 30x30.

Performs comparatively poorly in responsible promotional practices. Eli Lilly does not disclose whether sales agents are incentivised on other measures 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 (e.g., payments for attending events or promotional activities), unless required by local regulations or trade associations.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Eli Lilly has an average performance, with evidence of some of the components looked for by the Index: A continuous system to monitor activities, audits and formal processes to ensure third-party compliance with company standards. There is no evidence, publicly found or disclosed to the Index, of fraud-specific risk assessment or country risk-based assessment.

RESEARCH & DEVELOPMENT

Rank 19  Score 0.88

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 33% of the late-stage candidates. Eli Lilly has six projects including three late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on coronaviral diseases and tuberculosis. Of Eli Lilly’s three late-stage candidates targeting a priority product gap, one has evidence of an access plan in place, which is for the TBA-7371 / DprE1 Inhibitor. This project runs in partnership with the TB alliance.

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, 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 and/or are first-in-class molecules. Most target cancer.

Public policy to ensure post-trial access; commits itself to registering trialled products. Eli Lilly has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants with a serious condition and no alternative treatments are available. Once a product is approved, Eli Lilly commits itself to registering it in all countries where clinical trials for the product have taken place. The policy does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. Eli Lilly 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 R&D capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

PRODUCT DELIVERY

Rank 18  Score 1.25

Public commitment not to enforce patents in countries in scope. Eli Lilly publicly pledges to neither file nor enforce patents. This commitment applies to all Least Developed Countries.

Publicly discloses detailed 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. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

In addition to the older assets, Eli Lilly newly shared one IP asset with third-party researchers developing products for diseases in scope during the period of analysis. During the period of analysis Eli Lilly 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. The new agreement is in addition to previously agreed IP sharing agreement with the product development partnership TB Alliance.

No use of non-assert or licensing arrangements. Eli Lilly does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

No evidence of new products in scope filed for registration in the majority of high burden countries. Eli Lilly did not disclose evidence of filing any 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). Its most widely registered product dulaglutide (Trulicity®) for diabetes mellitus is reg-
No supranationally procured products. Eli Lilly has no products eligible for scoring in this indicator.

No evidence of access strategies for any of its health-care practitioner-administered products in scope of this analysis. Eli Lilly has not disclosed, either publicly or to the Index, access strategies for any of the four products (three oncology medicines and a treatment for ischaemic heart disease) assessed by the Index in this category.

No evidence of access strategies for any of its self-administered products in scope for this analysis. Eli Lilly has not disclosed, either publicly or to the Index, access strategies for any of the five products, assessed by the Index in this category. Four products in this category are indicated for diabetes mellitus treatment.

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

No supply chain capacity building initiatives included for evaluation. Eli Lilly 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.

Two health system strengthening initiatives meet all Good Practice Standards. Eli Lilly has average performance in this area, with limited information identified by the Index on the steps it takes to ensure the continuous supply of its medicine in countries in scope of the Index. Eli Lilly has policies and processes in place to align demand and supply, working together with local manufacturing and distribution sites. Eli Lilly reports having a global Product Shortage Prevention Strategy and a monitoring and reporting process for shortages in place. However, no details have been identified as to what these strategies and processes include.

Does not have a policy for reporting substandard and falsified (SF) medicines in countries in scope within the recommended time frame. Eli Lilly does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities. It has a public policy on tackling counterfeit products.

Donates in response to an expressed need and monitors delivery to end user. Eli Lilly has a public policy in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors the delivery until the end user.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Eli Lilly is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, the company is engaged in other structured donation programmes, such as the Life for a Child programme where it donates insulin lispro, human insulin analogue (Humalog®) for Type 1 diabetes mellitus in 37 countries since 2009.

Access to Medicine Foundation