Eli Lilly & Co.

Stock Exchange: New York Stock Exchange • Ticker: LLY • HQ: Indianapolis, Indiana, United States • Employees: 40,655

PERFORMANCE

Falls 3 places to 20th. Eli Lilly & Co.* falls across all Technical Areas, with weak performance, for example, in R&D, compounded by a comparative lack of public transparency in most areas of analysis.

Management: Falls 5 places to 14th. Despite public commitments associated with its 30x30 Program, it falls short on its public reporting of initiatives and discloses limited information about stakeholder engagement approaches.

Compliance: Falls 3 places to 15th. Compared to peers, it lacks a comprehensive ethical marketing code.

R&D: Falls 1 place to 19th. Eli Lilly falls to the lower ranks in R&D. It does not disclose access plans for any of its late-stage candidates.

Pricing: Falls 3 places to 20th. Falls behind peers primarily due to a lack of data transparency and lack of public commitments to equitable pricing.

Patents: Falls 2 places to 17th. Despite new engagement in patent transparency via Pat-INFORMED, falls back against stronger performers in the sharing of intellectual property.

Capacity: Falls 5 places to 20th. Evidence of initiatives only found for health system strengthening, but not enough information was disclosed to show they meet all good practice standards.

Donations: Falls 1 to 12th. Engaged in a structured donation programme for cancer, but lacks evidence of long-term sustainability.

OPPORTUNITIES

Improve transparency around access activities, objectives and outcomes. For example, Eli Lilly can publicly disclose measurable goals and key milestones for its newly announced 30x30 Program. Alongside this, the company can implement plans to measure the impact of this initiative, reporting on the results (whether positive or negative).

Develop access plans for key marketed products. Eli Lilly does not report having access plans in place for its cancer product vinblastine (Velban®, Velsar®), an off-patent first-line product on the 2017 WHO Model List of Essential Medicines (WHO EML) for the treatment of Kaposi sarcoma, Hodgkin lymphoma, and testicular cancer. Countries in scope shoulder a large proportion of the burden of Kaposi’s sarcoma. To alleviate this burden, equitable pricing strategies could be applied to priority countries such as Bangladesh, Brazil, China, Egypt, India, Malawi and Nigeria. Similarly, human insulin [rDNA origin] (Humulin®) for diabetes mellitus is an on-patent first-line product on the WHO EML with no reported access plans. The company could provide equitable pricing strategies for the product in priority countries including, Brazil, China, Dem. Rep.Congo, Ethiopia, India, Indonesia, Mexico, Tanzania and Uganda.

Establish access plans for more late-stage projects. Eli Lilly can establish access plans for projects across its pipeline, particularly those that are in late-stage development, including its nasal glucagon project for severe hypoglycaemia and DACRA-042, a novel oral medication for diabetes mellitus.

Review sales incentive structures. Eli Lilly can improve its commitment to ensure responsible sales practices by decoupling sales incentives from sales targets.

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*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. In 2018, Eli Lilly & Co. declined to submit data to the Access to Medicine Index.
Comparatively small pipeline: 27 R&D projects for diseases in scope (26 medicines; 1 platform technology).

Clinical candidates: 26, including lasmiditan for the treatment of acute migraine and a novel inhibitor for the treatment of tuberculosis.

Regulatory approvals: 1, abemaciclib (Verzenio™) for the treatment of HR+, HER2- metastatic breast cancer in combination with aromatase inhibitors.

R&D focus: non-communicable diseases (cancer and diabetes mellitus).

Access provisions: for 1 project, with provisions incorporated in partnership with the TB Alliance.

Comparatively small portfolio: 22 products (all medicines) for diseases in scope.

Portfolio focus: non-communicable diseases (diabetes mellitus and cancer).

Essential medicines: 36% of Eli Lilly’s medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

First-line treatments: 50% of Eli Lilly’s medicines have first-line indications for diseases in scope.

Of Eli Lilly’s 27 R&D projects, one is supported by access provisions: e.g., a Phase I candidate for the treatment of tuberculosis developed with the TB Alliance involves equitable pricing and supply strategies. None of its 15 late-stage projects have provisions.

Eli Lilly’s relevant pipeline is mainly split between cancer and diabetes mellitus projects. Its pipeline includes one of only seven platform technology projects in the collective pipeline: an automated insulin delivery (AID) system.

Eli Lilly’s portfolio includes products such as glucagon (GlucaGen®) for the treatment of severe hypoglycemia and several oral agents for the treatment of type 2 diabetes mellitus.

59% of Eli Lilly’s medicines are listed on the WHO EML and/or as first-line treatments: e.g., intravenous/oral vancomycin (Vancocin®) and the insulin glargine biosimilar Basaglar®.

Two business units: Human Pharmaceutical Products and Animal Health (Elanco). Its Human Pharmaceutical segment has five therapeutic areas (endocrinology; neuroscience; oncology; cardiovascular diseases; and immunology). Its prescription pharmaceutical business has two therapeutic areas (neurology; and oncology).

M&A news: 2017 acquisition of CoLucid, specialising in pain management for migraines. 2018 acquisition of ARMO BioSciences and AurKa Pharma, both focused on therapies for cancer.

Presence in emerging markets: In 2016, Eli Lilly reported sales in 72 countries in scope. Data for 2018 not available.

Revenue by segment (2017) - USD

Human pharmaceutical products 19,785 MN
Animal health products 3,085 MN
Total 22,871 MN

Statistics relate only to diseases and countries in scope.

* Figure excludes one project that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

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

***See Appendix IV for definition.
Eli Lilly & Co.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT
RANK 14  SCORE 3.00

Has a strong access-to-medicine strategy with executive-level responsibility. Eli Lilly is one of the 14 companies that performs strongly with regard to its access-to-medicine strategy, which aligns with its corporate strategies and includes access-related goals. The strategy currently centres around its Lilly 30x30 Program, aimed at delivering access to quality healthcare for 30 million people in resource-limited settings by 2030. The highest level of responsibility for access sits with an executive committee member.

Financial and non-financial access-related incentives to reward employees. Eli Lilly performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include compensation rewards, and its Access Excellence Awards recognising individual contributions.

One of 16 companies working on impact measurement. Eli Lilly measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments. For example, for its Lilly Expanding Access for People (LEAP) programme in China, the company reports committing to address local realities and medical needs, to help populations lacking effective access to healthcare. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Limited transparency about stakeholder engagement. Eli Lilly performs relatively poorly when it comes to the disclosure of its stakeholder engagement. It publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its processes for selecting who to engage with, nor its policy for ensuring responsible engagement. Neither does it report incorporating local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE
RANK 15  SCORE 2.06

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Eli Lilly has the Red Book Code of Business Conduct for governing business ethics. The company provides compliance training for employees on an annual basis. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some index criteria. Eli Lilly’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 and maintains an ethics and compliance monitoring programme. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of procedures to segregate duties, to ensure decisions are checked by another party.

Below average transparency regarding access-related practices. Eli Lilly publicly discloses its policy positions on access-related topics (e.g., its position on intellectual property and trade policy). It is one of the few companies in scope to have a policy that prohibits political financial contributions. The company discloses its membership of relevant organisations but not whether it provides financial support. It does not publicly disclose its policies for responsible engagement, nor its policy approach to payments made to healthcare professionals in countries in scope.

PUBLIC PRICING, MANUFACTURING & DISTRIBUTION
RANK 20  SCORE 0.88

Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope. Eli Lilly does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

No new products in scope filed for registration in the majority of priority countries. Eli Lilly has not filed any 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). Its most widely registered product, for diabetes mellitus, is registered in three out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

14% of products have equitable pricing strategies targeting priority countries. Eli Lilly’s overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 14% of its products for diseases in scope. These strategies apply to an average of 19% of priority countries. None of the strategies take into account any socioeconomic factors.

PUBLIC RESEARCH & DEVELOPMENT
RANK 19  SCORE 0.88

Publicly commits to R&D to meet public health needs. Eli Lilly has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on an internal review of needs unique to these countries. It does not report time-bound strategies for completing R&D projects for diseases in scope. Eli Lilly has one of the smallest pipelines in the Index with 27 projects. For diseases in scope where priorities exist, Eli Lilly is active in one project, which targets a priority R&D gap for tuberculosis.

No access provisions; process in place for setting them. Eli Lilly 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 malaria and tuberculosis that are developed in collaboration. Eli Lilly has not disclosed project-specific access provisions for any of its 15 late-stage R&D projects.

Public policy to ensure post-trial access; commits to registering trialed products. Eli Lilly has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Eli Lilly commits to registering it in all countries where clinical trials for the product have taken place.
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 17  SCORE 1.17**

Publicly discloses detailed information on
patent statuses. Like most of its peers, Eli Lilly
publicly discloses the patent statuses for small
molecules in scope via the Pat-INFORMED plat-
form. This will be periodically updated and
includes detailed information about patents,
including filing date, grant number, grant date
and jurisdiction.

No use of non-assert or licensing arrange-
ments. Eli Lilly does not engage in voluntary
licensing nor has it issued non-assert declara-
tions for products in scope.

Does not report newly sharing IP assets with
3rd-party researchers beyond existing agree-
ments. Eli Lilly reported existing agreements
with product development partnerships such as
the Drugs for Neglected Diseases initiative
(DNDi) and the Medicines for Malaria Venture
(MMV). During the period of analysis, beyond
existing agreements, the company reports no
instances where it newly shares IP assets with
third-party researchers developing products for
diseases in scope.

Public commitment not to enforce patents in
countries in scope. Eli Lilly commits publicly
to neither file for nor enforce patents related
to diseases within the scope of the Index.
This commitment applies in Least Developed
Countries.

**CAPACITY BUILDING**

**RANK 20  SCORE 0.34**

Two initiatives included for evaluation. Eli Lilly
has two capacity building initiatives that were
included for analysis by the Index; i.e., the initia-
tives demonstrably address a specific local need
and involve local partners. Companies could
submit a maximum of 25 initiatives across all
areas for assessment. Eli Lilly's initiatives were
identified for selection based on publicly availa-
ble information.

Two initiatives aimed at strengthening health
systems. Eli Lilly has two initiatives which meet
inclusion criteria in health system strengthening:
the Lilly MDR-TB Partnership and their partner-
ship with AMPATH. It does not publicly disclose
initiatives which meet inclusion criteria for any
other areas of capacity building.

Limited publicly available data on initiatives.
None of Eli Lilly's included initiatives meet all
the good practice standards looked for by the
Index. The company reported no information to
the Index about its health system strengthen-
ning initiatives, and publicly available information
is limited.

Does not provide evidence of reporting sub-
standard or falsified medicines to relevant
authorities. Eli Lilly has mechanisms in place for
the prevention and handling of counterfeit med-
icines. However, it does not provide evidence
that it systematically reports cases of substand-
ard or falsified medicines to relevant authorities
and/or WHO Rapid Alert.

**PRODUCT DONATIONS**

**RANK 12  SCORE 2.83**

**STRUCTURED DONATION PROGRAMMES: 3**

Responds to emergencies and humanitar-
ian crises and tracks delivery. Eli Lilly donated
medicines on the request of relief agen-
cies. For example, during the period of analy-
sis, it donated products in response to the 2017
Mexico earthquake. The company discloses that
such ad hoc donations are aligned with interna-
tional guidelines (issued by WHO, PQMD), and
it works, for example, with American Red Cross
and United Way Worldwide to ensure products
are rapidly delivered. It also monitors the deliv-
ery of the product until received by end user.

Three donation programmes covering diseases
and countries in scope. Eli Lilly's programmes
are focused on non-communicable diseases. All
three programmes are carried out in partner-
ship with partners including the International
Diabetes Foundation and numerous universities.
Its Life for a Child programme for type 1 diaabe-
tes mellitus supplies the insulin product lispro
(Humalog®) in 23 countries and has been ongo-
ing since 2009. As of 2017, the company reports
that 1.4 million vials of insulin were donated.

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

**INNOVATIVE PRACTICES**

Lilly Expanding Access for People (LEAP) builds
capacity in diabetes care.

**CHINA**

Training for primary care physicians in China to
increase their confidence and skills in managing
diabetes across all stages of the disease.