

RANK	SCORE
14 <sup>▲</sup>	2.11
16 (2016)	

# Boehringer Ingelheim GmbH

Stock Exchange: n.a. • Ticker: n.a. • HQ: Ingelheim am Rhein, Germany • Employees: 49,610

## PERFORMANCE

Rises 2 places to 14<sup>th</sup>. Boehringer Ingelheim launched a new access-to-medicine strategy that is directly overseen by the Board. It improves in Pricing and Capacity Building, but is comparatively weaker in R&D, Market Influence & Compliance and Product Donations.

**Management:** Falls 3 places to 17<sup>th</sup>. Launched a new access strategy, but fails to incentivise staff to achieve access objectives.

**Compliance:** Rises 4 places to 14<sup>th</sup>. Discloses policies for responsible engagement, but fails to publicly disclose financial support to relevant institutions.

**R&D:** Falls 3 places to 16<sup>th</sup>. Its R&D strategy lacks a public health rationale for diseases in scope, but improves its access plans during R&D.

**Pricing:** Rises 6 places to 12<sup>th</sup>. Significant improvement, with 84% of its portfolio covered by equitable pricing strategies, targeting priority countries.

**Patents:** Falls 2 places to 9<sup>th</sup>. Despite a broad geographic scope for its non-assert declaration, the company lags behind peers in patent transparency.

**Capacity:** Rises 5 places to 12<sup>th</sup>. Notable improvement in capacity building, with a focus on pharmacovigilance and health system strengthening.

**Donations:** Rises 2 places to 15<sup>th</sup>. Donates products in response to natural disasters, but has no long-term structured donation programmes.

## OPPORTUNITIES

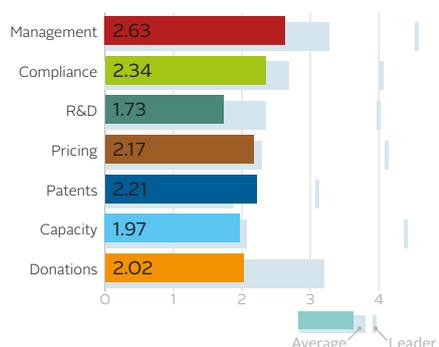
**Expand process to establish more access plans for all R&D projects.** Boehringer Ingelheim can expand its process to develop access plans during R&D to all in-house and collaborative R&D projects for all diseases in scope. It can follow a structured timeline to ensure that these plans are in place as soon as possible. Boehringer Ingelheim has an opportunity to ensure that access plans for both its marketed and investigational biosimilars in scope are established. Biosimilars have the potential to support affordability if access plans are developed. This applies to products such as Boehringer Ingelheim's insulin glargine biosimilar (Basaglar<sup>®</sup>) developed in collaboration with Eli Lilly, and its Phase III clinical biosimilar candidate, bevacizumab.

**Apply lessons from well-structured initiatives.** Boehringer Ingelheim's Angel's Initiative works to optimise the availability and quality of treatment for stroke patients. The initiative meets all of the good practice standards looked for by the Index, including good governance structures, processes to mitigate conflicts of interest, and monitoring and evaluation procedures. One of Boehringer Ingelheim's pillars of its new strategy for access is focused on solutions for adherence and awareness. When developing country-level initiatives under this pillar, the company can ensure that all initiatives meet the same standards as this one.

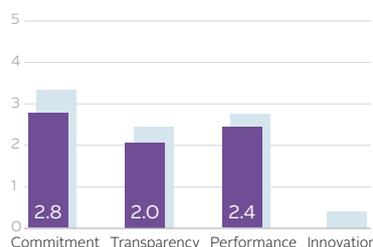
**Implement strategies to minimise the risk of non-compliance.** Boehringer Ingelheim can establish formal processes to ensure third-party compliance with standards of anti-corruption and ethical marketing. Alongside this, Boehringer Ingelheim can decouple its sales incentives from sales targets to incentivise responsible sales practices.

**Establish a clear and public post-trial access policy.** Boehringer Ingelheim can develop a clear stance on post-trial access that is aligned with the Declaration of Helsinki, detailing the conditions through which a clinical trial participant will be eligible for post-trial access. In addition, it can commit to registering all new products in the countries where clinical trials for these products have taken place.

Performance by technical area



Performance by strategic pillar



## CHANGE SINCE 2016

- Strengthened its commitment to access with responsibility at the board-level, and the establishment of the position of Head of Access to Healthcare and Global Health Policy.
- Reviewed and updated its access to medicine strategy with clear objectives focused on three strategic pillars: availability, sustainable access models, and innovative solutions for awareness and adherence.
- Expanded its patent filing and enforcement policy to abstain from enforcing patents in most low-income and low human development countries, and many middle-income countries across the company's entire human pharmaceuticals portfolio.
- In 2018, launched the 'In Reach Africa' programme, which aims to improve human and animal healthcare access in 10 African countries.
- Implemented a new Global Code of Conduct for ethical marketing and compliance in 2018, aligned with the IFPMA Code of Practice and the UN Global Compact principles.

**PIPELINE** for diseases and countries in scope

**Comparatively large pipeline:** 111 R&D projects (all medicines) for diseases in scope.

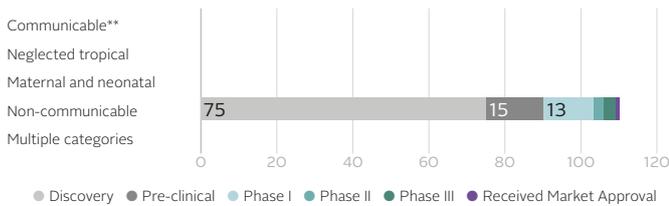
**Clinical candidates:** 20, including a bevacizumab biosimilar candidate for the treatment of lung cancer.

**Regulatory approvals:** 1, afatinib (Gilotrif®) as an expanded indication for the treatment of metastatic non-small cell lung cancer.

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

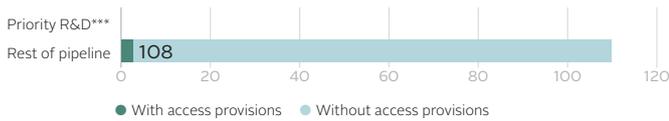
**Access provisions:** for 3 projects, all including equitable pricing, registration and supply strategies.

**Projects in the pipeline: 111\***



Boehringer Ingelheim's pipeline includes a Phase III biosimilar for bevacizumab for the treatment of lung cancer. The original bevacizumab (Avastin®) has been approved for several cancer types including breast and colorectal.

**Projects for R&D priority targets with access provisions: 0**



Of Boehringer Ingelheim's 111 R&D projects, three are supported by access provisions: e.g., nintedanib for colorectal cancer will have equitable pricing, registration and supply strategies. Two of its seven late-stage projects have provisions.

**BUSINESS CONTEXT**

**Three business units:** Prescription Medicine; Animal Health; and Biopharmaceuticals. Its prescription medicine segment has six therapeutic areas (respiratory disorders; cardiovascular diseases; metabolic diseases; central nervous system diseases; oncology; and immunology).

**M&A news:** 2017 divestment of consumer healthcare business to Sanofi, in exchange for

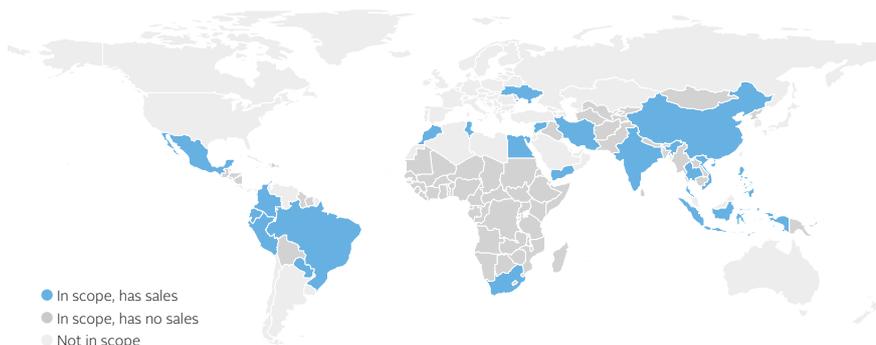
Merial, Sanofi's animal health business.

**Presence in emerging markets:** In 2018, Boehringer Ingelheim reports sales in 20 countries in scope; three less than in the 2016 Index. It reports that almost 25% of its sales in 2017 came from the Asia, Australia and Africa region.

**Net sales by segment (2017) - EUR**

Human Pharmaceuticals	12,621 MN
Animal Health	3,901 MN
Biopharmaceuticals	678 MN
Other Sales	43 MN
Discontinued Operations	813 MN
<b>Total</b>	<b>18,056 MN</b>

**Sales in countries in scope**



Statistics relate only to diseases and countries in scope.

\* Figure excludes one project that does 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.

**PORTFOLIO** for diseases and countries in scope

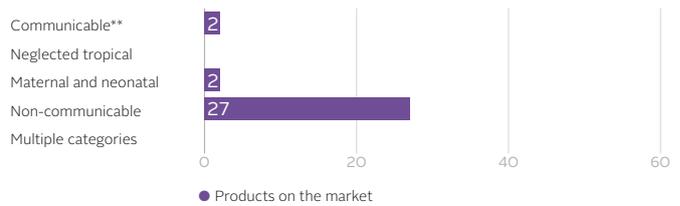
**Comparatively small portfolio:** 31 products for diseases in scope (30 medicines; 1 contraceptive method).

**Portfolio focus:** non-communicable diseases (diabetes mellitus, chronic obstructive pulmonary disease and asthma).

**Essential medicines:** 32% of Boehringer Ingelheim's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

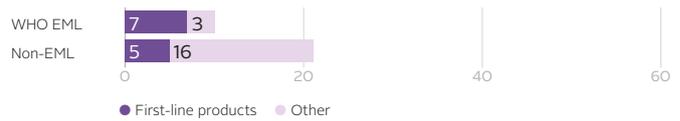
**First-line treatments:** 39% of Boehringer Ingelheim's medicines have first-line indications for diseases in scope.

**Products on the market: 31**



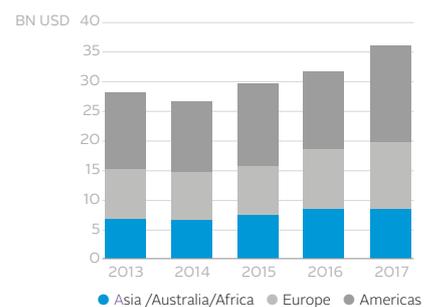
Boehringer Ingelheim's portfolio includes products such as fenoterol hydrobromide (Partusisten®) for preterm labour/birth and several medicines for diabetes mellitus.

**Essential medicines with first-line indications: 7**



48% of Boehringer Ingelheim's medicines are listed on the WHO EML and/or as first-line treatments: e.g., the sulfonylurea gliquidone (Glurenorm®) and the insulin glargine biosimilar Basaglar®, respectively, for diabetes mellitus.

**Net sales by geographic region**



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

# Boehringer Ingelheim GmbH

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 17 SCORE 2.63

**Has a strong access-to-medicine strategy with board-level responsibility.** Boehringer Ingelheim is one of 14 companies that performs strongly with regards to its newly launched access-to-medicine strategy, which is aligned with its corporate strategies. The strategy has a focus on availability, sustainable access models, awareness and adherence. The highest level of responsibility for access sits with a board-level committee.

**No evidence of access-related incentives for employees.** Boehringer Ingelheim does not disclose details of how it incentivises employees (financially and non-financially) to perform on access-related issues. It is one of only two companies that do not demonstrate evidence of such incentives.

**Measures and monitors outcomes and progress; not impact.** Boehringer Ingelheim measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on objectives and targets. For example, for its Angels Initiative on patient care, Boehringer Ingelheim reports having trained 33,936 healthcare workers across various countries in the last two years. However, it does not report measuring the impact of its initiatives.

**Discloses who it engages with, incorporates local perspectives into strategies.** Boehringer Ingelheim publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

### MARKET INFLUENCE & COMPLIANCE

RANK 14 SCORE 2.34

**Does not report processes for ensuring third-party compliance with standards.** Boehringer Ingelheim has a code of conduct relating to ethical marketing and anti-corruption, namely its Anti-Bribery and Anti-Corruption Policy. It provides compliance training for employees on an annual basis. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, expected performance for sales agents is based

solely on sales targets.

**Internal control framework meets some Index criteria.** Boehringer Ingelheim's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an internal auditing department for the whole company, involving both internal and external resources—that also applies to third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of having a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

**Below average transparency regarding access-related practices.** Boehringer Ingelheim publicly discloses its policy positions on access-related topics (e.g., its corporate policy on supply chain integrity). It does not disclose political contributions in countries in scope. Boehringer Ingelheim discloses its membership of relevant institutions but not whether it provides financial support. The company discloses its policies for responsible engagement through its code of conduct. It does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

### RESEARCH & DEVELOPMENT

RANK 16 SCORE 1.73  
PROJECTS: 111 IN CLINICAL DEVELOPMENT: 20

**R&D commitment has limited public health rationale.** Boehringer Ingelheim has made a specific commitment to R&D for diseases in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries lacks an evidence-based public health rationale including internal assessments and calls for action from external sources like WHO. It lacks time-bound strategies for completing R&D projects for diseases in scope and evaluating progress toward these targets. Boehringer Ingelheim has one of the largest pipelines in the Index with 111 projects. Boehringer Ingelheim is active in R&D for non-communicable diseases, for which a globally accepted priority list does not exist.

**Access provisions in place for 29% (2/7) of late-stage candidates.** Boehringer Ingelheim has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for non-communicable diseases where it is actively involved in low- and middle-income

countries. In general, Boehringer Ingelheim develops access plans for R&D projects in Phase III of clinical development. To date, Boehringer Ingelheim has project-specific access provisions in place for two of its late-stage R&D projects, both of which are being conducted in-house.

**No policy for post-trial access.** Boehringer Ingelheim does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Additionally, it does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 12 SCORE 2.17  
PRODUCTS: 31  
COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 26

**Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope.** Boehringer Ingelheim 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.** Boehringer Ingelheim 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 five out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

**84% of products have equitable pricing strategies targeting priority countries.** Boehringer Ingelheim's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 84% of its products for diseases in scope. These strategies apply to an average of 41% of priority countries. All of these strategies apply inter-country pricing strategies; these take into account an average of two socioeconomic factors. Boehringer Ingelheim also applies an

equitable pricing strategy to one further product informed by a public health rationale.

**Has both globally consistent recall guidelines for countries in scope and processes to track products.** Boehringer Ingelheim has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

## PATENTS & LICENSING

RANK 9 SCORE 2.21

### Does not publicly disclose patent statuses.

Unlike most of its peers, Boehringer Ingelheim does not disclose the status of its products for diseases and countries in scope.

**Uses non-assert declarations to enable generic supply.** Boehringer Ingelheim has a non-assert declaration in place for one compound (for diseases in scope). Its non-assert declaration, for nevirapine (Viramune XR®), encompasses 135 low- and middle-income countries in scope. It has not issued any non-exclusive voluntary licensing agreements for products in scope.

**Does not share IP assets with 3<sup>rd</sup>-party researchers.** Boehringer Ingelheim reports no instances where it shares IP assets with third-party researchers developing products for diseases in scope, during the period of analysis.

**Public commitment not to enforce patents in countries in scope.** Boehringer Ingelheim commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies to most low-income, low-development countries, and in a subset of lower-middle income countries and upper-middle income countries.

## CAPACITY BUILDING

RANK 12 SCORE 1.97

### Eight initiatives included for evaluation.

Boehringer Ingelheim has eight capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Boehringer Ingelheim submitted 24.

**Focused on supporting pharmacovigilance systems.** Boehringer Ingelheim has initiatives which meet inclusion criteria in all areas of capacity building, except R&D. Most of these initiatives are focused on pharmacovigilance capacity building and health system strengthening. Two of these health system strengthening initiatives are focused on stroke.

### One initiative meets all applicable good practice standards:

#### -Angels Initiative

Boehringer Ingelheim's remaining included initiatives typically have goals in place, but fall short on monitoring progress and outcomes and ensuring good governance structures are in place.

### Timely approach to reporting substandard or falsified medicines to relevant authorities.

Boehringer Ingelheim provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to local regulatory authorities within the period recommended by stakeholders (maximum seven days).

## PRODUCT DONATIONS

RANK 15 SCORE 2.02

STRUCTURED DONATION PROGRAMMES: 0

**Responds to emergencies and humanitarian crises and tracks delivery.** Boehringer Ingelheim donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to hurricanes in Haiti and the Dominican Republic. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Americares, MAP International and Direct Relief to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

**No donation programmes covering diseases and countries in scope.** Boehringer Ingelheim does not have any structured donations programmes that were active during the period of analysis in any countries in scope.

## BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.