

RANK	SCORE
<b>12</b>	<b>2.84</b>
14 (2018)	

# Boehringer Ingelheim GmbH

Stock Exchange: n.a. • Ticker: n.a. • HQ: Ingelheim am Rhein, Germany • Employees: 51,015

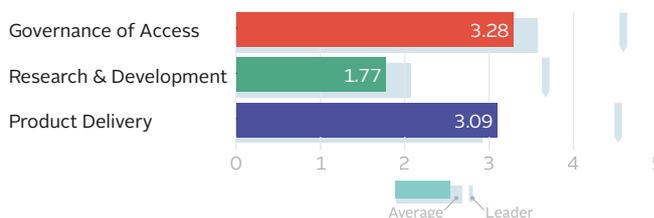
## PERFORMANCE IN THE 2021 INDEX

12<sup>th</sup> place. Overall, Boehringer Ingelheim is a middle-performing company. It shows a strong performance in its access approach for specific products and markets but the company has a small-sized priority R&D pipeline with no late-stage candidates.

**Governance of Access:** 10<sup>th</sup> place. Boehringer Ingelheim is a middle-performing company in this area. Its access-to-medicine strategy is clearly linked to its business model, but it lacks access-related incentives for senior executives or in-country managers.

**Research & Development:** 11<sup>th</sup> place. Boehringer Ingelheim is a middle-performing company in this area. It has some R&D projects that address a public health need in LMICs, with the majority covered by an access plan. Yet, the company has a small-sized priority R&D pipeline compared to peers with no projects in late-stage development and does not engage in R&D capacity building.

How score was achieved



**Product Delivery:** 9<sup>th</sup> place. Boehringer Ingelheim performs average in this area. It newly shared some IP assets with third-party researchers. It has access strategies in place for some of its products in countries of all assessed income levels. Yet, there is no evidence of new products in scope filed for registration in the majority of high-burden countries. The company engages in some strong health system strengthening initiatives and has engaged in the development and implementation of multiple new inclusive business models.

## OPPORTUNITIES FOR BOEHRINGER INGELHEIM

**Develop access-oriented incentive structures.** Boehringer Ingelheim has an access-to-medicine strategy, integrated within its overall corporate strategy. It can develop financial and non-financial access incentives for executives and in-country managers. Furthermore, it can review sales incentive structures to adopt a balanced scorecard approach consistently, thus ensuring that sales agents are not solely incentivised on sales volume targets.

**Follow peers in publicly disclosing patent status.** Boehringer Ingelheim can disclose patent information publicly to meet the actions of all other 19 companies in scope of the Index that currently disclose patent information for small molecules in scope via the Pat-INFORMED platform or via their own channels.

**Improve access to patented products on WHO EML.** Boehringer Ingelheim engages in equitable pricing for some its products. The company has in total six patented products which are on the 2019 WHO Model List of Essential Medicines (WHO EML). The company can further prioritise expanding access to these products, such as dabigatran (Pradaxa®) for the prevention of stroke and afatinib dimaleate (Giotrif®/Gilotrif®) first line treatment for metastatic non-small cell lung cancer, and patented medicines for type 2 diabetes mellitus that are not on WHO EML, such as empagliflozin (Jardiance®), empagliflozin/linagliptin (Glyxambi®) and empagliflozin/metformin (Synjardy®), by increasing affordability and supply using mechanisms such as equitable pricing and/or non-exclusive voluntary licensing in countries in scope.

## CHANGE SINCE THE 2018 INDEX

- Announced partnership with Defeat-NCD to tackle the premature death, sickness, disability, and associated social and economic impacts from non-communicable diseases.
- Formed a Sub-Saharan operating unit, partnering with local distributors, provides guidance on logistical management and supports with knowledge on Good Distribution Practice (GDP) training and auditing to improve distribution.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Engaged in new ways to share IP via a new programme, opnMe: providing free access to compounds and their associated properties for research in areas, such as hepatitis, malaria, HCV, HIV, non-communicable diseases (NCDs) and via the Covid-19 Therapeutics Accelerator.
- Launched a new initiative in Kenya as part of the In Reach Initiative with AMPATH, 'Kuza Afya' for cardiovascular disease, hyper-tension and diabetes community health screening and referrals.
- Launched a new initiative in Kenya as part of In Reach Africa initiative with PharmAccess to use mobile technology to address awareness and access barriers in hypertension and diabetes.
- Launched a new pilot programme in Pakistan in collaboration with the OIE to eliminate rabies by donating the vaccine Rabisin® and dogs identification collars.

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 segments:** Human pharmaceuticals; Animal Health; Biopharmaceutical contract manufacturing  
**Therapeutic areas:** Respiratory diseases; Cardiovascular and metabolic diseases; Oncology; Central nervous system diseases; Ophthalmology (retina health), Inflammation, Emerging areas (infectious diseases)  
**Product categories:** Innovative medicines; Animal health; Biosimilars.

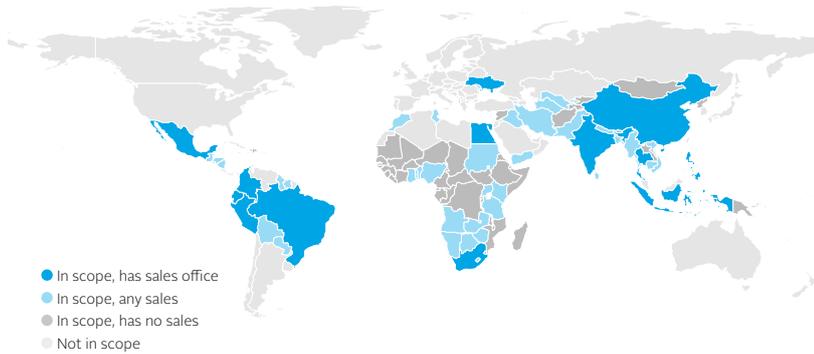
**M&A news:** Acquired AMAL Therapeutics (oncology) in 2019; acquired the preclinical pipeline of Northern Biologics (oncology) and NBE-Therapeutics (oncology) in 2020.

**Boehringer Ingelheim's products are sold in 53 out of 106 countries in scope.** Boehringer Ingelheim has sales offices in 13 countries, sells via suppliers in 36 countries and via pooled procurement into 4 additional countries.

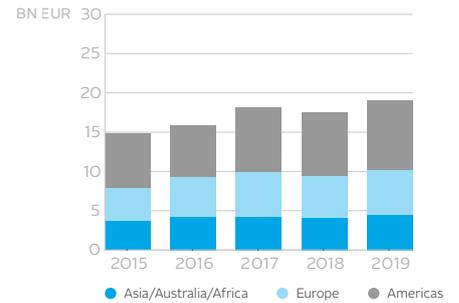
**Net sales by segment (2019) – EUR**

Human Pharmaceuticals	13.961 bn
Animal Health	4.035 bn
Biopharmaceutical Contract Manufacturing	0.786 bn
Other sales	0.041 bn
Discontinued operations	0.174 bn
<b>Total</b>	<b>18.997 bn</b>

**Sales in countries in scope**



**Sales by geographic region**



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

**PIPELINE** for diseases and countries in scope

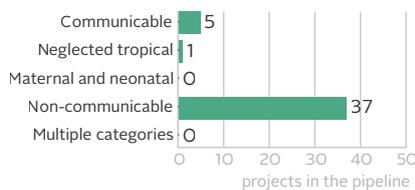
Boehringer Ingelheim has a total of 43 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 6 projects. The other 37 R&D projects target other diseases in scope. The projects targeting priority diseases include tuberculosis (2 projects). Of the projects targeting other diseases in scope, the focus is on kidney diseases (4), diabetes (4) and oncology (19).

Boehringer Ingelheim has no projects in late-stage development targeting a priority disease. 9 R&D projects are in late-stage development that address a public health need in LMICs.\* Evidence of access planning was in place for 89% of these projects.

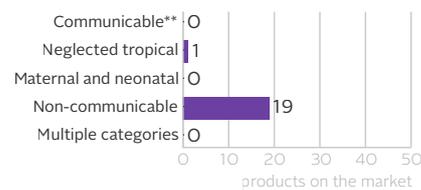
**PORTFOLIO** as selected for analysis by the Index

Boehringer Ingelheim has 19 medicines in scope, 12 of which are on patent. 58% of these medicines (11) are on WHO's EML. In addition the company markets 1 vector control product. The off-patent medicines target non-communicable diseases (NCDs) such as pulmonary diseases (3), cardiovascular diseases (3) and diabetes. The on-patent medicines target NCDs such as diabetes (5), pulmonary diseases (3), cardiovascular diseases (3) and oncology. The vector control product targets rabies. Access strategies were analysed for 8 products on Boehringer Ingelheim's portfolio – supranationally procured (1) or nationally procured HCP-administered (2) and self-administered products (5).

**43 projects in the pipeline**



**20 products as selected for analysis by the Index†**



**Breakdown of projects#**

Xentuzumab a humanized immunoglobulin G (IgG) 1 monoclonal antibody targeting breast cancer.

	Pre-clinical	Phase 1	Phase 2	Phase 3	Approval	Total	W. access plans
Targets established R&D priorities	1	0	0	0	0	1	0
Addresses needs of LMICs*	0	0	6	2	1	9	8
Other projects in scope	0	27	0	0	1	28	

**Breakdown of products**

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	6	6			12
off patent	5	2			7
Vaccines	0	0			0
Diagnostics			0		0
Other***				1	1

\*50 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.

\*\*\*Other includes vector control product. See Appendix I for definitions.  
 †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.

# Boehringer Ingelheim GmbH

## GOVERNANCE OF ACCESS

RANK 10

SCORE 3.28

**Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy.** Boehringer Ingelheim performs strongly. It has an Access to Healthcare Approach, including both human and animal health. The strategy covers all therapeutic areas in which the company is involved, namely the non-communicable diseases (NCDs). The highest responsibility for access lies directly with the board, with the Access to Healthcare Steering committee.

**Does not provide evidence of financial or non-financial access-related incentives at the managerial level.** Although it has a clear access strategy, Boehringer Ingelheim performs relatively poorly here. It does not demonstrate evidence of having access-related incentives for senior executives or in-country managers.

**Publicly discloses outcomes of a subset of its access-to-medicine activities.** Boehringer Ingelheim performs well in transparency of access activities. It publicly

discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example the Making More Health initiatives and through the IFPMA Global Health Progress platform.

**Performs comparatively poorly in responsible promotional practices.** Boehringer Ingelheim's sales agents are solely incentivised on sales volume targets. The company sets incentives based on sales targets at the individual level for agents. Except for Ukraine where it discloses to EFPIA<sup>||</sup>, the company 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), nor does it disclose a policy limiting such transfers.

**Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.** Boehringer Ingelheim has an average performance, demonstrating some of the components looked for by the Index: fraud-specific risk assessment, audits (both internal and external, covering third parties and in all countries where it operates), country risk-based assessments and formal processes to ensure third-party compliance with company standards. It does not, however, demonstrate sufficient evidence of a continuous system to monitor activities.

**Publicly supports the Doha Declaration on TRIPS and Public Health.** Boehringer Ingelheim publicly shares support of the Doha Declaration on TRIPS and Public Health. It views the Declaration as a mechanism offering more juridical certainty to countries which may intend to use the system. It can dissent from industry association positions, when such a case presents itself.

## RESEARCH & DEVELOPMENT

RANK 11

SCORE 1.77

**Access planning processes for some R&D projects for diseases in scope.**

**A small-sized priority R&D pipeline compared to peers, with no late-stage priority R&D candidates.** Boehringer Ingelheim has six projects but no late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including tuberculosis. As no late-stage candidates targeting a priority product gap are in the pipeline, there is no evidence of any access plans.

**Some projects address a public health need in LMICs\*, with 89% of these projects covered by access plans.** In this analysis, Boehringer Ingelheim has nine 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 have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Boehringer Ingelheim provides evidence of access plans for eight of these projects.

**Public policy to ensure post-trial access; commits itself to registering trialed products.** Boehringer Ingelheim 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 who have a life-threat-

ening condition. Once a product is approved, Boehringer Ingelheim commits itself to registering it in all countries where clinical trials for the product have taken place. This 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.** Boehringer Ingelheim performs poorly in this indicator. The company submitted five initiatives aimed at building R&D capacity, but none were included for analysis as they did not meet the inclusion criteria.

## PRODUCT DELIVERY

RANK 9

SCORE 3.09

**Public commitment not to enforce patents in countries in scope.** Boehringer Ingelheim publicly commits to neither file for nor enforce patents. This commitment applies to most Least Developed Countries in scope and low-income countries in scope and in a subset of lower and upper middle-income countries in scope.

**Does not publicly disclose information on patent statuses.** Unlike all its peers, Boehringer Ingelheim does not disclose the patent status of its products for diseases and countries in scope.

**Shares some IP assets with third-party researchers.** Compared to its peers, Boehringer Ingelheim has newly shared some IP assets with third-party researchers devel-

oping products for diseases in scope. This includes initiatives such as the opnMe program and the COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries.

**No use of non-assert or licensing arrangements.** Boehringer Ingelheim does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope.

**No evidence of new products in scope filed for registration in the majority of high burden countries.** Boehringer Ingelheim 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, dabigatran etexilate (Pradaxa<sup>®</sup>) for stroke prevention, is registered/has been filed for registration in 38 countries in scope, including Haiti and Botswana.

**Has access strategies for all supranationally procured products in scope for this analysis.** Boehringer Ingelheim performs above average in securing access for its only product evaluated which is procured supranationally.<sup>†</sup> The company reports equitable pricing strategies and donates the veterinary rabies vaccine Rabisin<sup>®</sup> for non-eligible World Organization for Animal Health countries.

<sup>||</sup> Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare professionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

**Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis.** Boehringer Ingelheim performs well in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for the two products concerned. It makes efforts to reach additional patients through the use of equitable pricing strategies. The company is able to provide evidence of how patient reach has been increased through the approaches used.

**Has access strategies for its self-administered products for some countries in scope of this analysis.** Boehringer Ingelheim has average performance in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for three out of the five products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies. The company is able to provide evidence of how patient reach has been increased through the approaches used.

**Two manufacturing capacity building initiatives included for evaluation.** Boehringer Ingelheim performs below average in this indicator. Boehringer Ingelheim submitted the maximum of five initiatives, of which two met all criteria for inclusion. The initiatives, which support Contract Manufacturing Organisations to meet global quality regulations and requirements, did not meet all the Good Practice Standards<sup>§</sup> as the company could not sufficiently demonstrate how the initiatives aim for sustainability.

**Four supply chain capacity building initiatives included for evaluation.** Boehringer Ingelheim performs below average in this indicator. Boehringer Ingelheim submitted the maximum of five initiatives, of which four met all criteria for inclusion. The initiatives include training on Good Distribution Practices for storage, specifically cold and deep-frozen storage. None of the initiatives submitted by the company met all Good Practice Standards<sup>§</sup>, as the company did not provide sufficient evidence on having clear goals and objectives and long-term aims.

**Four health system strengthening initiatives meet all Good Practice Standards.** Boehringer Ingelheim performs above average in this indicator, with four health system strengthening initiatives that were included for analysis and meet all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- The Angels initiative aims to improve and expand stroke care, at present in 103 countries, of which 38 are in scope of the Index. The initiative has reportedly reached over 35,000 healthcare professionals treating an estimated 3.3 million patients in registered hospitals.
- The Kuzu Afya initiative, a cardiovascular disease management programme in partnership with AMPATH, has screened over 70,000 patients in rural western Kenya and trained 50 healthcare professionals.

**Has engaged in the development and implementation of new inclusive business models.** Boehringer Ingelheim performs above average when it comes to implementing scalable inclusive business models that aim to meet the

access needs of populations at the base of the pyramid in countries in scope. It has contributed to multiple new models focused on NCD care, including Akiba ya Roho for informal settlements, and partnerships with social entrepreneurs, including Healthy Entrepreneurs, Chronic Drugs Medical Scheme, Jacaranda Maternity and Yako Medical.

**The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index.** Boehringer Ingelheim performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. For example, for handling shortages or stock-outs, the company reports that it has a notification and communication procedure that applies to all countries where they have presence and products on the market. This also includes some Least Developed Countries.

**Has a policy for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days.** Boehringer Ingelheim has a policy for reporting SF medicines to national regulatory authorities within 7 days. It does not, however, distinguish reporting time frames for cases which only require visual inspection to be confirmed. If visual inspection of packaging is sufficient, the reporting timeline might be shorter, but this is not a standard procedure.

**Donates in response to an expressed need and monitors delivery to end user.** Boehringer Ingelheim has a 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. For example, it donated essential medicine to three countries in 2018-2019 to the Supporting Healthy Mothers project.

**Publicly commits to the achievement of elimination, eradication or control goals in its structured donation programme.** One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Boehringer Ingelheim publicly commits itself to eliminating rabies by donating the rabies vaccine or medicine, Rabisin<sup>®</sup>, from 2019 to 2030 in Pakistan as a pilot.

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

§ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.