

RANK	SCORE
9	3.36
13 (2021)	

Bayer AG

Stock exchange: XFRA • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 99,637

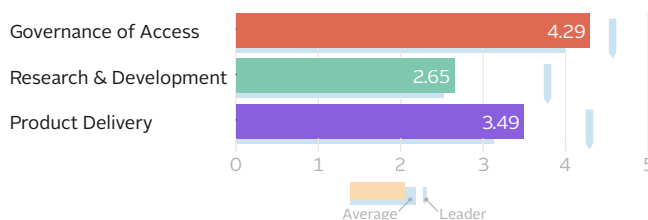
PERFORMANCE IN THE 2022 INDEX

9th place. Bayer ranks among the top ten companies of the Index. It performs strongly in access strategies for healthcare practitioner-administered products. The company has also strengthened its performance in inclusive business models and in access planning during R&D.

Governance of Access: 8th place. Bayer performs well in this area. It has an access-to-medicine strategy integrated into its overall corporate strategy, although the strategy covers only some of its therapeutic areas. It incentivises senior executives and in-country and regional managers to perform on access-to-medicine goals and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 10th place. Bayer's performance is average in this area. It now has a structured access planning process in place and applies this to most late-stage pipeline candidates. Although it has a small-sized priority R&D pipeline, its access plans include the most countries in scope of

How score was achieved



the Index compared to its peers. However, the company's performance in R&D capacity building is below average.

Product Delivery: 9th place. Bayer has an above average performance. The company has comprehensive access strategies for some of its products but lacks access strategy examples in low-income countries for its self-administered products. Bayer has also both scaled-up and piloted inclusive business models and performs well in supply chain capacity building.

OPPORTUNITIES FOR BAYER

Ensure all late-stage R&D projects have comprehensive access plans. Bayer has introduced a structured process for access planning beginning in Phase II of clinical development. It has access plans in place for 80% of late-stage candidates analysed. The company can expand its access plans to all R&D projects from Phase II onwards.

Expand access to on-patent cancer products in lower-middle and low-income countries, such as darolutamide (Nubeqa®). Bayer has access strategies in UMICs for darolutamide, indicated for prostate cancer and listed on the WHO Model List of Essential Medicines. The company can provide evidence of expanding access to the product via equitable access strategies and registration in lower-middle income countries, low-income countries and countries with a high burden of disease such as Guyana and Suriname. In addition, the company can expand access to sorafenib (Nexavar®), indicated for thyroid and liver cancer, via equitable access strategies and registration in LICs and in countries with a high burden of disease such as Bolivia, Guinea and Gambia.

Expand technology transfer initiatives for reproductive health commodities to additional countries. Bayer has previously transferred technology for its hormonal contraceptive products to manufacturers in LMICs such as Algeria and Morocco. Bayer can expand the geographic scope of these technology transfers to build manufacturing capacity and improve regional availability in countries or regions with specific access gaps.

CHANGES SINCE THE 2021 INDEX

- Established an ESG committee in January 2022 at the supervisory board level.
- Invests over EUR 400 million to construct a production site for contraceptives in Costa Rica and expand a production site in Finland, both of which will supply to LMICs.
- Introduced a structured framework to include access planning in the development process early on for all its pipeline projects (both in-house and collaborative).
- Received first approval for nifurtimox (Lampit®) indicated for paediatric Chagas disease.
- Began to report disaggregated R&D investment data to Policy Cures Research.
- Opened two new hubs in Pakistan and the Philippines for The Challenge Initiative (TCI), a platform that enables governments to scale up family planning approaches for the urban poor.
- Extended its commitment with the World Health Organization (WHO) for an additional five years to accelerate control and elimination of neglected tropical diseases including the donation of medicines for treatment of chagas disease and African trypanosomiasis (sleeping sickness), estimated at USD 8 million.
- Donated over USD 3.8 million in products to the UNFPA as well as USD 1 million for logistical supply chain support during the COVID-19 pandemic.
- Received WHO Prequalification (PQ) (RH100) for levonorgestrel-releasing intrauterine system (Mirena®). All contraceptive products sold under supranational programmes have now received WHO PQ.

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.

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.

SALES AND OPERATIONS

Business segments: Consumer health, crop science and pharmaceutical.

Therapeutic areas: Cardiology, oncology, ophthalmology, radiology and women's health.

Product categories: Innovative medicines.

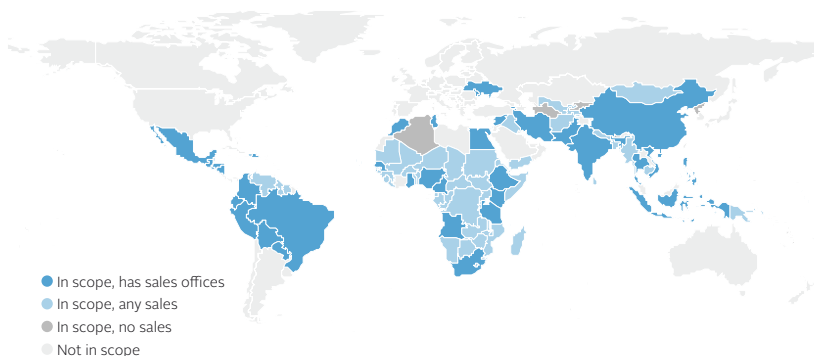
M&A news: Bayer acquired Vividion Therapeutics in August 2021 for USD 1.5 billion.

Bayer's products are sold in 95 out of 108 countries in scope of the Index. Bayer has sales offices in 38 countries, and sells via suppliers and/or pooled procurement in an additional 57 countries.

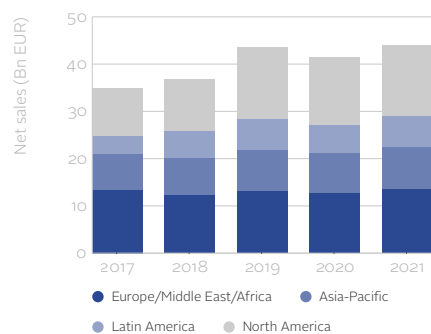
Net sales by segment (2021) – in EUR

Crop science	20.21 bn
Pharmaceutical	18.35 bn
Consumer health	5.29 bn
Total	43.85 bn

Sales in countries in scope



Sales by geographic region



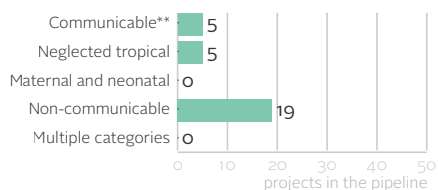
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

Bayer has a total of 29 R&D projects in scope with ten of these projects targeting priority diseases. The other 19 R&D projects target other diseases in scope. Six projects concern vector control products. Of the projects targeting priority diseases, the focus is on malaria (three projects). Of the projects targeting other diseases, the focus is on kidney diseases (4) and oncology (10).

Ten R&D projects are in late-stage development that target either a priority disease (4) or address a public health need in LMICs (6).^{*} Evidence of access planning was in place for 80% of these projects: four targeting a priority disease and four addressing a public health need in LMICs.

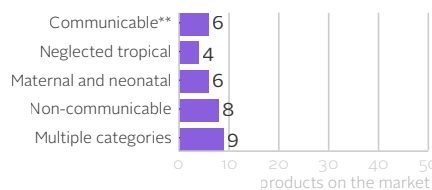
29 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

Bayer has 13 medicines in scope and seven contraceptive methods and devices. Of the medicines, eight are on patent. Of the 20 medicines and contraceptive products, 55% (11) are on the WHO EML. In addition, the company markets 13 vector control products. The off-patent medicines target mainly women health, these include contraceptive methods (5) and target neglected tropical diseases, such as human African trypanosomiasis (3). The on-patent medicines mainly target non-communicable diseases such as cancer (5) and kidney diseases (2). The vector control products target communicable diseases such as dengue and chikungunya (8) and malaria (12).

33 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other ^{***}	Total
Targets established R&D priorities	2	0	0	1	1	2	4	10
Addresses needs of LMICs [*]			4	2	0	4	0	10
Other projects in scope			3	3	2	1	0	9

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	6			8
off patent	5	0			5
Vaccines	0	0			0
Contraceptives	4	3			7
Diagnostics			0		0
Other [†]				13	13

^{*}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). [†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. [‡]Other includes vector control products.

Bayer AG

GOVERNANCE OF ACCESS

RANK 8

SCORE 4.29

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. Bayer performs strongly. It has an access strategy aiming at increasing the societal impact of its business activities. The strategy covers most therapeutic areas in which the company is involved, mainly focusing on women's health and access to contraceptives. The highest responsibility for access lies directly with the board, with the Chief Sustainability Officer. Furthermore, in 2022 Bayer established an ESG committee at supervisory board level to oversee access-related goals.

Provides evidence of financial and non-financial access-related incentives at the executive level. Bayer performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to sustainability goals.

Publicly discloses outcomes of its access-to-medicine activities. Bayer performs strongly in transparency of access activities. It

publicly discloses its commitments, measurable goals, objectives and targets for sustainability and improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Patient Access Charter and ESG Report.

Performs above average in responsible promotional practices. Bayer's sales agents are not solely incentivised on sales volume targets. However, Bayer sets sales incentives at the individual level for agents. The company 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 law, but it does have a Fair Market Value policy to facilitate appropriate transfers.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Bayer performs strongly, demonstrating evi-

dence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Bayer publicly shares support of intellectual property rights in line with the TRIPS Agreement, while highlighting a need for appropriate measures in place for the development of innovative products. 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, Bayer, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 10

SCORE 2.65

Access planning processes encompass all projects in the pipeline. Bayer has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. Bayer begins developing access plans for R&D projects no later than Phase II of clinical development.

A small-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (4/4) of the late-stage candidates analysed. Bayer has ten projects, including four late-stage candidates, in its pipeline that target a priority product gap. These focus on various disease areas including malaria, Chagas disease, Zika, dengue and chikungunya. Of Bayer's four late-stage candidates targeting a priority product gap, all have evidence of access plans. These plans range from registration to a partnership with the Drugs for Neglected Diseases *initiative* (DNDI). A

notable example is the development of paediatric nifurtimox (Lampit®) to treat Chagas disease. Registration in additional endemic high disease-burden countries is planned for this project.

Some projects address a public health need in LMICs,* with 67% (4/6) of late-stage projects covered by access plans. In this analysis, Bayer has six 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. The projects mainly focus on cancer and kidney diseases. Bayer provides evidence of access plans for four of these projects. These access plans mainly focus on plans for registration in countries in scope and the development of an equitable pricing strategy.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, Bayer does disclose fully disaggregated R&D investment data to Policy Cures Research.

Two R&D capacity building initiatives included for evaluation. Neither initiative included for analysis meet all Good Practice Standards. Bayer's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. Bayer builds R&D capacity in Vietnam, by providing technical assistance to PATH in developing an affordable and sustainable COVID-19 vaccine.

*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 9

SCORE 3.49

Public commitment not to enforce patents in countries in scope. Bayer publicly pledges to neither file for nor enforce patents. This commitment applies in LICs only, for all its products in scope of the Index.

Publicly discloses information on patent status. Like most of its peers, Bayer discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Bayer discloses patent information such as filing date, grant number, grant date and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Bayer does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Bayer does not engage in voluntary licensing for products in scope of the Index.

Filed to register new products in six countries in scope on average. Bayer did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely registered is rivaroxaban (Xarelto®), an antithrombotic medicine for several indications, including prevention of stroke. It has been filed in 68 countries within scope of the Index, including 12 LICs. Bayer has filed rivaroxaban and sorafenib (Nexavar), indicated for liver and thyroid cancer, in more than half of the top ten high burden countries. sorafenib has been filed in Ecuador, Ethiopia, Honduras, Mongolia, Thailand and Vietnam.

Has access strategies for all its supranationally procured products in scope of this analysis. Bayer has an average performance in securing access for products procured supranationally. For three of the four products assessed in this category, the company demonstrates that it applies the same pricing strategies both in UNFPA countries eligible for supply from such procurers and in at least one country not eligible. The company provides evidence of patient reach, reporting that between 24 and 25 million women received access to modern contraception annually during the reporting period.

Has access strategies for the healthcare practitioner-administered product in scope of this analysis. Bayer performs above average in this area. For the product assessed, levonorgestrel-releasing intrauterine system (Mirena®/LNG-IUS), the company provides examples of access strat-

egies in countries of all assessed income levels (UMIC, LMIC, LIC). It also makes efforts to reach additional patients through donations, supranational agreements and tenders. For example, in Brazil, Bayer has donated this product through the International Contraceptive Access (ICA) Foundation. In Egypt, Bayer reached an agreement with the Ministry of Health to include the contraceptive in the government's Family Planning sector, and it will be provided for free to patients that cannot afford the contraceptive price while strengthening the health system via healthcare practitioner training and awareness campaigns. Bayer provides evidence of an increase in patient reach.

Has access strategies for its self-administered products for some countries in scope for this analysis. Bayer performs below average in this area. For three of the five products assessed, the company provides evidence of pricing strategies considering payers' ability to pay in UMIC and LMIC country examples. Bayer was able to secure rivaroxaban (Xarelto®) full reimbursement in Colombia in January 2022. In addition, it introduced a new patient programme that offers the first treatment cycle free of charge and supports patients in obtaining reimbursement coverage. Evidence that about 500 patients have been included in the programme since December 2021 is provided.

One of the three manufacturing capacity building initiatives included meets all Good Practice Standards. Bayer'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 the initiative that met all GPS, since 2019, Bayer has built manufacturing capacity of its partners by making it mandatory for all contract manufacturing organisation sites to be audited according to the industry-wide Pharmaceutical Supply Chain Initiative (PSCI) standards.

All three supply chain capacity building initiatives included for analysis meet all Good Practice Standards. Bayer's performance is above average in this area. The number of initiatives meeting all inclusion criteria is average, but more initiatives meet all GPS than what is average for this indicator. For example, Bayer is a partner in the PSCI where it helps suppliers meet PSCI standards in several LMICs including India, China, Kenya and Nigeria.

Three of the four health systems strengthening initiatives included meet all Good Practice Standards. Bayer's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all GPS for this indicator. For example, Bayer is a partner in The Challenge Initiative (TCI) — a platform that enables govern-

ments in countries in scope of the Index to scale up high-impact family planning approaches for the urban poor. This initiative meets all GPS.

Has engaged in scaling up three and piloting two inclusive business models. Bayer performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Through the Bayer Foundation's Women Empowerment Award, Bayer annually awards EUR 25,000 to scale the social enterprises of five female entrepreneurs across sub-Saharan Africa. An example from this cycle is Whispa health, a platform that connects users to local medical centres, with the aim to be Africa's preferred sexual and reproductive health access provider.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Bayer is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, has established multi-source networks for active pharmaceutical ingredients in addition to in-house production and is involved in supply chain capacity building initiatives. The company also manages a buffer stock of relevant products based on local medical needs assessments that inform supply risk management.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Bayer has a policy for reporting SF medicines to national health authorities within seven days for the most severe risk category. It 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. Bayer 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.

Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria. In one programme, Bayer publicly commits to controlling Chagas disease in endemic countries in Latin America as well as eliminating human African trypanosomiasis in endemic countries in Africa. The company publicly commits to donating nifurtimox (Lampit®) and suramin (Germanin®) for as long as needed until goals are reached.