

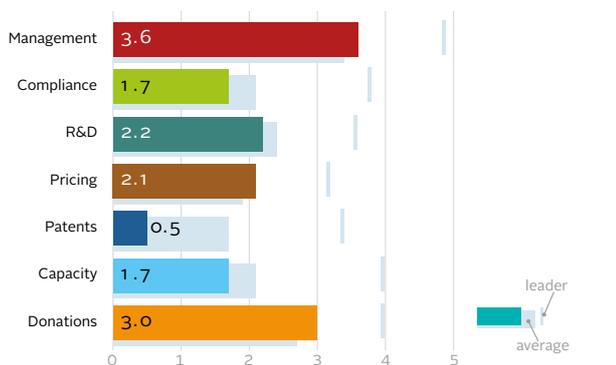
RANK	SCORE
12 <sup>v</sup>	2.03
10 (2014)	

# Bayer AG

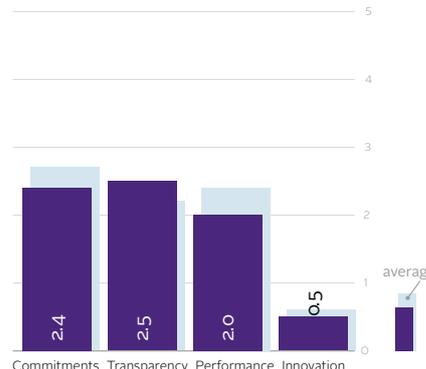


Stock Exchange: XFRA • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 116,800

## Ranking by technical area



## Ranking by strategic pillar



## PERFORMANCE

Bayer falls two places, out of the top ten. Its modest improvements are frequently overshadowed by peers. It has made some improvements in how it measures progress toward access-related goals, and has time-bound targets tied to its R&D commitment to addressing neglected tropical diseases. Bayer is comparatively active in strengthening pharmacovigilance systems. Elsewhere, however, it has dropped: for exam-

ple, it is comparatively less transparent than in 2014 about its market influencing activities and compliance efforts. Its equitable pricing and product registration performance has not kept pace with peers. Bayer provides limited evidence that it takes a pro-access approach to IP management. Bayer is engaged in large-scale structured donation programmes for Chagas disease and Human African Trypanosomiasis (HAT).

## CHANGE SINCE 2014

- Improves its measurements for tracking performance toward access targets, but it still lacks clear processes for incorporating local stakeholders' perspectives in its access initiatives.
- Has equitable pricing strategies for the same number of products as in 2014.
- Has improved its accountability for its sales agents' pricing practices, by providing pricing guidelines for all local sales agents.
- Still does not publish its patenting approach.
- Is less active in building capacity beyond the pharmaceutical value chain and in local manufacturing.
- Continues to engage in donation programmes targeting Chagas disease and Human African Trypanosomiasis that cover all endemic countries.

## OPPORTUNITIES

### Broaden access strategy beyond NTDs.

Bayer can broaden its access strategy beyond neglected tropical diseases (NTDs) to include ischaemic heart disease, diabetes, lower respiratory infections and zoonotic diseases. In addition, Bayer can review its pipeline to assess the relevance of its R&D projects for people in low- and middle-income countries. For relevant projects, it can put access plans in place before products gain approval.

**Develop an approach to local stakeholder engagement.** Bayer can develop processes for selecting and engaging with local stakeholders to help ensure local needs are addressed through its R&D, capacity building and access management approaches. Local stakeholder

engagement is crucial for understanding local needs and for responding with suitable, sustainable access strategies.

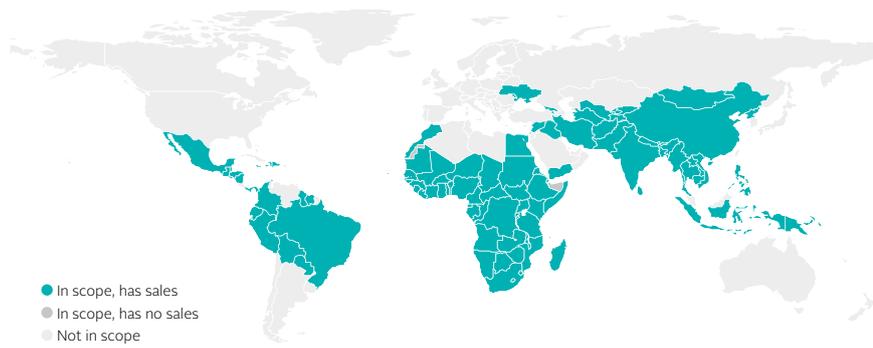
**Expand application of equitable pricing.** Bayer can apply the intra-country equitable pricing model that it uses for contraceptives to other products (e.g., vector-control products, and for NTDs) and to a range of countries in scope.

**Give a public position on filing for and enforcing patents.** Bayer can develop and disclose a public position on the filing for and enforcement of patents. Thirteen other companies in the Index have already taken this step. This would help give drug procurement agencies and generic manufacturers confidence about where Bayer

would assert patent rights for current and future products. To complement this approach, Bayer can publicly disclose the status of its patents, clearly showing where products are on and off patent, and when patents are due to expire.

**Join efforts to combat antimicrobial resistance.** Bayer has three antibiotics on the WHO Model Essential Medicines List (EML) that are used in clinical practice and are important for low-resource settings. The company can increase access to these medicines, while ensuring their responsible use. Bayer can join global efforts to address antimicrobial resistance, for example by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

Sales in countries in scope



SALES AND OPERATIONS

Bayer reorganised its corporate structure in 2015. With the spin-off of Bayer MaterialScience (Covestro), its new corporate structure comprises three divisions (Pharmaceuticals, Consumer Health and Crop Science) and its Animal Health business unit. Its pharmaceuticals portfolio is focused on: cardiology, women's healthcare, oncology, haematology, ophthalmology and radiology. CropScience has a broad

portfolio of seeds and chemical and biological pest management solutions, including products for controlling and preventing vector-borne diseases. In 2014, the company acquired Merck & Co's Consumer Care business for USD 14.2 bn. In 2016, Bayer signed a merger agreement with Monsanto for USD 66 bn. Bayer has a broad geographic presence, covering 102 of the countries in the scope of the Index.

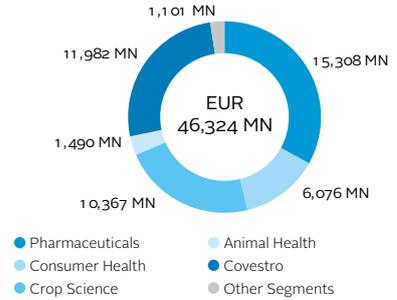
PORTFOLIO AND PIPELINE

Bayer has a mid-sized portfolio of 34 relevant products and a small pipeline of three R&D projects that address the needs of people in countries in scope.

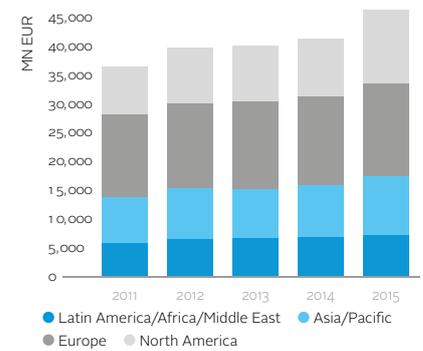
Its portfolio consists of 27 medicines and contraceptives, and seven vector-control products (all pesticides). Its vector-control products are all registered for the prevention of malaria and/or dengue. Bayer's relevant medicine portfolio has a strong focus on contraceptive methods. The company is also active in infectious diseases, hypertensive and ischaemic heart disease.

Regarding its R&D pipeline, Bayer has a new R&D project to adapt emodepside for onchocerciasis, and is working on two adaptations of nifurtimox (Lampit®) for Chagas disease. The adaptations of nifurtimox have been in clinical development since at least 2014 (the previous Index), and clinical development of emodepside for use in humans began in December 2014. Bayer's R&D projects target independently identified high-priority product gaps.

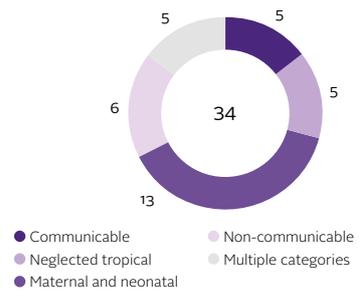
Sales by segment (2015)



Sales by region

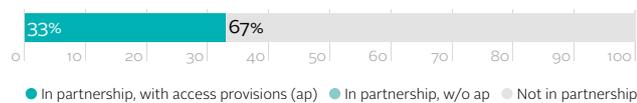


Products per disease category



Approximately one third of Bayer's portfolio targets women's health, mainly via contraceptives.

Pipeline projects



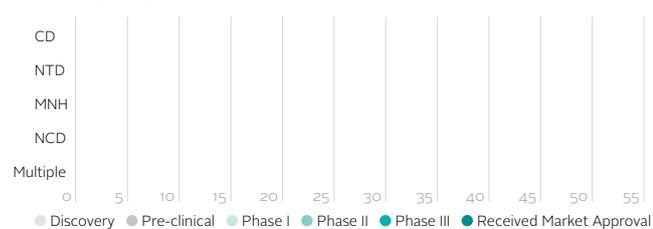
In December 2014, Bayer entered a product development partnership with the Drugs for Neglected Diseases initiative to develop emodepside for use in humans. Bayer has committed to providing this product at cost price.

First-line treatments and essential medicines



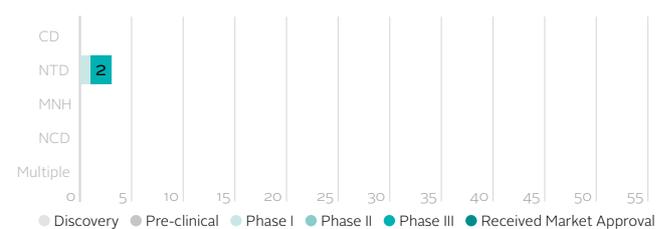
A comparatively high proportion of Bayer's relevant products are listed on the WHO EML and/or considered first-line treatments. These include the contraceptives moxifloxacin (Avelox®) and nifurtimox (Lampit®).

Pipeline by stage of development



Bayer is not developing any innovative products for diseases in scope for use in low- and middle-income countries.

Adaptive medicines and vaccines



Bayer is adapting its veterinary medicine emodepside to treat onchocerciasis in humans. It is also adapting Lampit® for Chagas disease, developing a paediatric formulation and a shorter treatment regimen (to 60 and 30 days).

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 11 SCORE 3.6

**Maintains position despite limited improvement.** Bayer maintains its position, improving the way it measures progress toward access-related targets. However, at the local level, its stakeholder engagement activities are executed only on an ad-hoc basis.

**Access activities are embedded in business strategy.** Bayer's activities for improving access include sustainable and commercially-viable strategies, such as equitable pricing, patient-access and assistance programmes, as well as sustainable philanthropy and donation programmes. The company states that providing access is an essential part of its long-term licence to operate.

**Centralised performance management system in place.** Bayer uses a centralised system to collect quantitative and qualitative data for tracking progress regarding access activities. This information is only partially disclosed.

**Ad-hoc engagement with local stakeholders.** Bayer has a clear and structured approach to engaging with stakeholders at a regional and international level. However, it does not have a specific approach for engaging with local stakeholders: these engagements are managed on a case-by-case basis.

### MARKET INFLUENCE & COMPLIANCE

RANK 14 SCORE 1.7

**Drops six positions due to lower transparency.** Bayer's transparency has fallen on several issues, relative to peers. However, it is one of the companies that pledges not to make any political contributions to political parties, politicians or candidates for political office.

**Low performance in ethical marketing.** While Bayer's marketing code of conduct is consistent with industry standards, it does not enforce compliance of third-party sales agents. Furthermore, Bayer only uses sales targets to incentivise sales agents, rather than access-linked incentives. Bayer does not publish information about marketing activities in countries within scope.

**Some transparency on lobbying activities.** Bayer discloses its policy positions related to

access to medicine, in relation to access to high-quality medicines and products and the development of sustainable health care systems. In addition, Bayer's position supports the protection of both the international patent system and its own intellectual property worldwide. It also discloses information about its liaison offices and their budgets in several cities worldwide. Bayer does not publish its policy for preventing conflicts of interest.

**Not transparent about breaches of laws and codes.** Bayer did not provide any information regarding its breaches of codes, regulations and laws and any consequent settlements. However, since 2014, the company was found to have breached codes of conduct five times for cases related to unethical marketing.

**Makes no political contributions.** Bayer states that it does not make any donations or contributions of any kind to political parties, politicians or candidates for political office. It provides details of financial contributions made to industry associations during the period of analysis.

**Has enforcement processes and actively tracks compliance.** The company has enforcement processes and disciplinary measures in place. It does not report whether disciplinary measures have been taken during the period of analysis. Bayer provides detailed information about its process for auditing compliance with its codes of conduct: auditing activities take place following an annual audit plan, in addition to unannounced ad-hoc audits. In 2015, the company performed 198 audits.

### RESEARCH & DEVELOPMENT

RANK 12 SCORE 2.2

**Maintains mid-ranking position, with no significant improvements.** Looking at Bayer's relevant pipeline, it is the same size as in 2014, and the company maintained a mid-ranking performance in R&D partnerships and IP-sharing.

**Committed to R&D for NTDs, with clear targets set.** Bayer commits to developing new products for NTDs. This includes applying for WHO pre-qualification for its adaptation of emodepside to treat onchocerciasis in humans by 2023.

**Measures in place to ensure R&D partnerships promote access, but no clear policy.** Within its collaboration with Drugs for Neglected

Diseases initiative to develop emodepside for use in humans, Bayer has committed to providing the product at cost price. However, it does not commit to ensuring access-oriented terms are systematically included in its research partnerships.

**Takes measures to ensure clinical trials are conducted ethically.** Bayer has policies in place and takes measures to ensure its in-house and outsourced clinical trials are conducted ethically.

**Has system for sharing patient-level data, yet disclosure is incomplete.** Bayer's has a policy of making clinical trial results available, but only for approved drugs. This falls short of stakeholders' expectations that the results of all trials will be disclosed. Nevertheless, the company does provide scientific researchers with access to patient-level data upon request via [clinicalstudydatarequest.com](http://clinicalstudydatarequest.com).

**Does not disclose terms of R&D partnerships.** Bayer has a general position to not disclose the terms and conditions of its R&D partnerships. However, access plans for its emodepside collaboration (for onchocerciasis) have been published by its partner, the Drugs for Neglected Diseases initiative: this makes the future accessibility of this product for populations in need more predictable.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 11 SCORE 2.1

**Drops seven places due to relatively poor performance in equitable pricing and registration.** Bayer falls out of the top five, into the bottom 10 companies in 2016. This is due to a fall in its performance in equitable pricing and registration. Disappointingly, Bayer shows no evidence that it has implemented the new differential pricing framework that it was piloting in 2014.

**Limited consideration of socio-economic factors when setting prices.** Bayer has the same equitable pricing strategies as in 2014: all for contraceptives. Some (8%) of its products have pricing strategies that target almost half of the relevant priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). However, its inter-country equitable pricing strategies only take affordability and no other socio-economic factors into account.

**Pricing guidelines for all sales agents.** Bayer has provided pricing guidelines to all of its local sales agents (third party wholesalers and distributors) and has internal controlling systems in place to monitor the implementation of its pricing policies.

**Very low transparency regarding product registrations.** Bayer has registration targets for a sub-set of relevant diseases in a sub-set of low-income countries. But it has not committed to registering new products within a set time-frame. In practice, Bayer provides no details on where it has filed to register its newest products for sale. In addition, it does not publish its criteria for deciding where or when to register its products.

**Consistent recall guidelines.** Bayer has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Bayer does not publish whether it has issued recalls.

**Adaptations of brochures and packaging to address range of needs.** Bayer facilitates the rational use of its products by providing instructions in locally prevalent languages, by using pictograms for populations with low literacy levels and by using blister packs to improve product stability in hot and humid conditions.

## PATENTS & LICENSING

RANK 18 SCORE 0.5

**Laggard in Patents & Licensing.** Bayer drops 10 positions in this area, to 18th place. There is limited public evidence that it takes an access-oriented approach to managing its intellectual property.

**Very low transparency regarding patenting strategy.** Bayer does not have a public policy for patent filing and enforcement. It does not publish the status of its patents in countries in scope. It has an internal policy not to file for patents in Least Developed Countries.

**Does not engage in licensing and makes no public commitment to doing so in future.** Bayer does not engage in licensing, nor does it publicly acknowledge the potential usefulness of licensing as a strategy for access-oriented product deployment.

**No clear position regarding the Doha Declaration.** Bayer does not publish its position on the Doha Declaration on the TRIPS agreement and public health.

**Absence of competition-related breaches.** Bayer was not found to have been the subject of breaches, fines or judgements relating to competition law during the period of analysis.

## CAPACITY BUILDING

RANK 13 SCORE 1.7

**Strength in building pharmacovigilance capacity outweighed by poor performance elsewhere.** Bayer demonstrates a relatively strong approach to strengthening pharmacovigilance systems but is comparatively weak in other areas, particularly in building capacities beyond the pharmaceutical value chain and in manufacturing. It does not consistently target local needs.

**Strongest area is in pharmacovigilance capacity building.** Bayer voluntarily shares safety data with authorities upon request and updates safety labels in relevant countries. It has a number of diverse activities for strengthening local pharmacovigilance systems, including an innovative initiative in this area (see below).

**Builds local manufacturing capacity, but only in-house.** Bayer makes a general commitment to build manufacturing capacity in countries in scope. The company undertakes a small number of capacity building activities in a range of relevant countries (including Brazil, China, India and Indonesia), but these are only directed at in-house staff. These activities focus on the industry standards for Good Manufacturing Practices (GMP).

**Weak performance in building health-related capacity outside the pharmaceutical value chain.** Bayer's approach to health-related philanthropic projects is relatively weak: it includes impact measurement but does not target local needs, sustainability, or specific objectives. Bayer supports capacity building initiatives not directly related to the production and distribution of medicines in Kenya and Uganda but does not demonstrate how it mitigates conflicts of interest.

► **Innovation: open-source pharmacovigilance tool.** In 2015, Bayer co-founded a Special Interest Group within the International Society of Pharmacovigilance. The group brings together Southeast Asian regulatory authorities and international experts to develop and share innovative risk-minimisation methods and tools, including an open-source tool for developing customised risk-management guidelines.

## PRODUCT DONATIONS

RANK 8 SCORE 3.0

**Bayer remains in 8th place.** Bayer has one of the highest numbers of donation programmes for NTDs, all carried out in cooperation with WHO.

**Wide-scale NTD donation programmes.** Bayer is engaged in long-term donation programmes for NTDs: involving nifurtimox (Lampit®) for Chagas disease and Gambian-type Human African Trypanosomiasis (HAT), and suramin

(Germanin®) for Rhodesian-type HAT. These programmes cover all endemic countries. They provided treatments for over ten thousand people during the period of analysis.

**Committed to supporting WHO for HAT and Chagas disease.** Since 2004, Bayer has committed to supporting WHO in its battle against Human African Trypanosomiasis (HAT) and Chagas disease. Under its current supply agreement, Bayer provides a million Lampit® tablets annually.

**Close collaboration with WHO for monitoring.** Bayer donates products via WHO pre-selected partners, who then report to Bayer. Reporting intervals are agreed before a donation is carried out. The company conducts external interviews and discussions with partners.

**Makes ad hoc donations for disaster relief and in emergencies.** Since 2014, Bayer made 69 separate ad hoc donations for disaster relief and public health emergencies, including following the 2016 Nepal earthquake and 2014-2015 Ebola epidemic.

### Disclaimer

As a multi-stakeholder and collaborative project, the findings, interpretations and conclusions expressed herein may not necessarily reflect the views of all members of the stakeholder groups or the organisations they represent. The report is intended to be for information purposes only and is not intended as promotional material in any respect.

The material is not intended as an offer or solicitation for the purchase or sale of any financial instrument. The report is not intended to provide accounting, legal or tax advice or investment recommendations. Whilst based on information believed to be reliable, no guarantee can be given that it is accurate or complete.

### Copyright

No part of this report may be reproduced in any manner without the written permission of the Access to Medicine Foundation. The information herein has been obtained from sources which we believe to be reliable, but we do not guarantee its accuracy or completeness. All opinions expressed herein are subject to change without notice.