

RANK	SCORE
16▼	1.88
12 (2016)	

Bayer AG

Stock Exchange: Frankfurt Stock Exchange • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 123,352

PERFORMANCE

Falls from 12th place in 2016 to 16th. Despite maintaining key donation programmes, Bayer performs comparatively poorly in its approach to equitable pricing, and its transparency around IP management is low.

Management: Falls 5 places to 16th. Comparatively poor performance on reporting access commitments.

Compliance: Rises 4 places to 10th. Although it holds a comparatively average standard of transparency, it continues to incentivise sales agents against sales targets.

R&D: Rises 4 places to 8th. With a mid-ranking performance, it lacks a process to develop access plans during R&D, but considers access for a key paediatric product.

Pricing: Falls 4 places to 15th, with a comparatively low proportion of equitable pricing strategies applied in priority countries.

Patents: Holds 18th place. One of only two companies without a public commitment to not enforce and/or file patents in countries in scope.

Fails to disclose patent statuses.

Capacity: Falls 1 place to 14th. Focus on pharmacovigilance, with no initiatives meeting all good practice standards.

Donations: Holds at 8th place. Maintains three structured donation programmes committed to the elimination of two NTDs.

OPPORTUNITIES

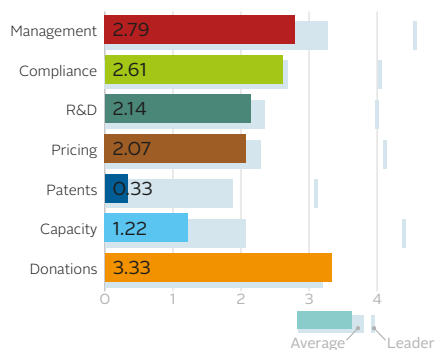
Review IP management approaches. Bayer can look to adopt a public, access-oriented IP management approach. This would include a public stance on not filing for or enforcing patents related to diseases in scope in Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries. Eighteen other companies in the Index have already taken this step. Bayer can also publicly disclose the status of its patents, clearly showing where products are on- and off-patent, and when patents are due to expire. This can be achieved either through self-disclosure or through Pat-INFORMED, a platform to promote the accessibility of patent information for health agencies tasked with procurement of medicines.

Expand consideration of affordability across contraceptive products. Currently the company has equitable pricing strategies for two products in the scope of the Index. Recalling its 2012 commitment at the London Family Planning Summit, Bayer could apply equitable pricing strategies to more of its contraceptive products, including drospirinone/ethinylestradiol (Yasmin®), estradiol valerate/norethisterone enantate (Norigynon®), levonorgestrel (Microlut®) and levonorgestrel releasing intrauterine system (Mirena®) - all first line products on the 2017 WHO Model List of Essential Medicines (WHO EML).

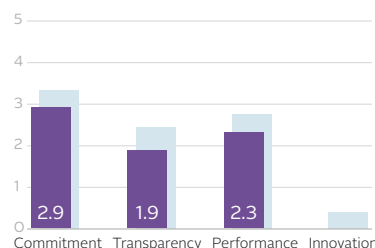
Develop a process to establish more access plans for R&D projects. Bayer can develop a clear approach to establish access plans for R&D projects earlier in the development phase that take into account the specific considerations necessary for each project. It can develop this approach for both in-house and collaborative projects for all diseases in scope, with a clear timeline for developing, refining and executing access plans to ensure broad and rapid access.

Review incentives for sales agents. Bayer can improve its commitment to ensure responsible sales practices by decoupling sales incentives from sales targets. Removing an emphasis on sales targets is recognised as a mechanism for ensuring rational prescribing, and critical for a company like Bayer that produces antibiotics and other products which are often inappropriately used.

Performance by technical area



Performance by strategic pillar



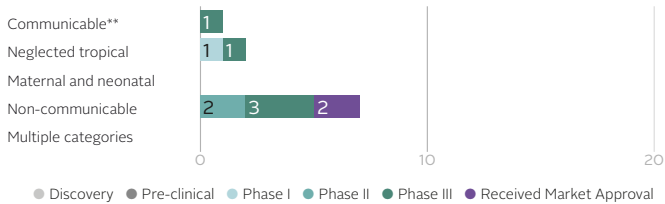
CHANGE SINCE 2016

- Joined Access Accelerated with a pilot programme focused on deep vein thrombosis (DVT) in Ghana.
- Partnered with Goodbye Malaria with commitments to expand access to WHO-recommended vector control products and to continuing to develop new vector control products to control and eliminate malaria.
- Files to register the majority of its most recently approved products in the majority of corresponding priority countries.
- Commits to expand its successful youth-centric health programmes under the umbrella of the World Contraception Day (WCD) and the associated "It's Your Life – It's Your Future" campaign.
- Reports that it newly extends enforcement processes for its code of conduct to third parties.

PIPELINE for diseases and countries in scope

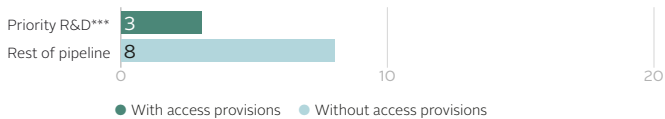
Comparatively small pipeline: 11 R&D projects for diseases in scope (10 medicines; 1 vector control product).
Clinical candidates: 9, including finerenone for the treatment of diabetic kidney disease and tedizolid (Sivextro®) for the treatment of pneumonia.
Regulatory approvals: 2, including copanlisib (Aliqopa™) for the treatment of follicular lymphoma.
R&D focus: non-communicable diseases (cancer) and neglected tropical diseases (Chagas disease).
Access provisions: for 3 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 11*



Bayer's pipeline is made up entirely of clinical candidates and newly approved products. This includes a Phase III candidate for an expanded indication of the antibiotic Sivextro® (tedizolid) for lower respiratory infections.

Projects for R&D priority targets with access provisions: 3



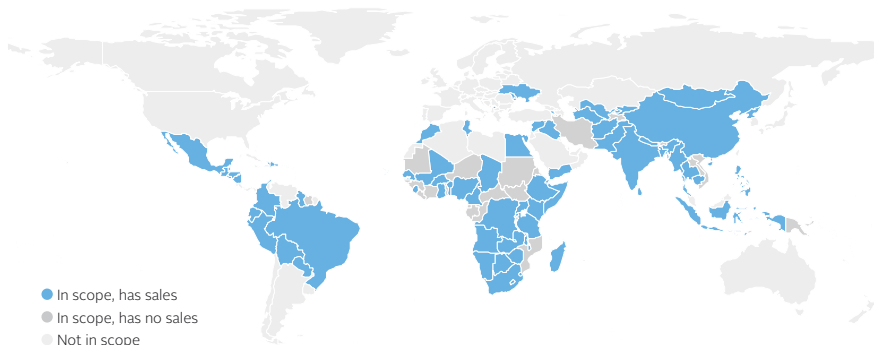
Of Bayer's 11 R&D projects, three are supported by access provisions (3 out of 11): e.g., paediatric nitrofurane (Lampit®) for Chagas disease has plans for WHO prequalification and registration. One of its nine late-stage projects has provisions.

BUSINESS CONTEXT

Four business units: Pharmaceuticals; Consumer Health; Crop Science; and Animal Health. Its pharmaceutical segment has five main therapeutic areas (cardiology, oncology, gynaecology, haematology and ophthalmology).
M&A news: 2018 acquisition of Monsanto, an agrochemical and agricultural biotechnology company; divestment of the agricultural business assets to German company BASF, the largest

chemical producer in the world.
Presence in emerging markets: In 2018, Bayer reports sales in 70 countries in scope; 32 less than in the 2016 Index. It reports that more than one-third of its sales in 2017 came from Asia-Pacific and Latin America.

Sales in countries in scope



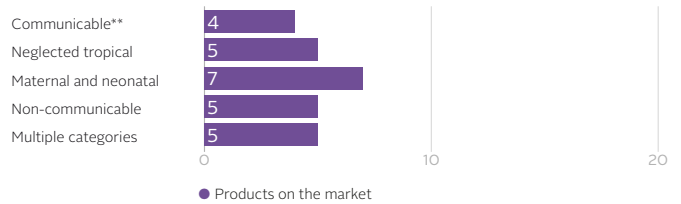
Statistics relate only to diseases and countries in scope.

* 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

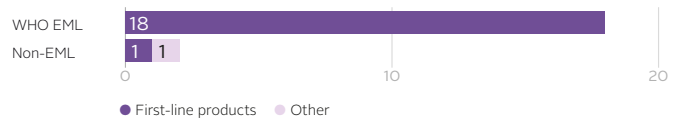
Comparatively small portfolio: 26 products for diseases in scope (13 medicines; 7 contraceptive methods; 6 vector control products).
Portfolio focus: maternal & neonatal health conditions (contraceptive methods), communicable diseases (malaria) and neglected tropical diseases (dengue and chikungunya).
Essential medicines: 90% of Bayer's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 95% of Bayer's medicines have first-line indications for diseases in scope.

Products on the market: 26



Bayer's portfolio includes products such as several insecticides for application on bed nets including Aqua Reslin®, Ficam® and Aqua K-Othrine® to prevent the transmission of malaria and other insect-borne diseases.

Essential medicines with first-line indications: 18

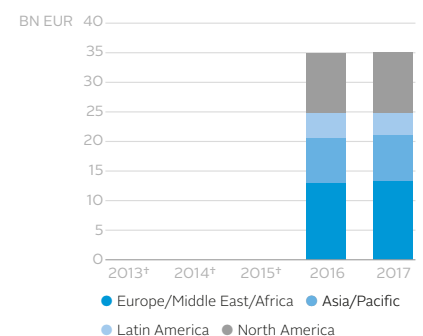


95% of Bayer's medicines are listed on the WHO EML and/or as first-line treatments: e.g., nifurtimox (Lampit®) and contraceptives including the levonorgestrel-containing implant Jadelle®.

Net sales by segment (2017) - EUR

Pharmaceuticals	16,847 MN
Consumer Health	5,862 MN
Crop Science	9,577 MN
Animal Health	1,571 MN
All other segments	1,142 MN
Reconciliation	16 MN
Total	35,015 MN

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.
 † Data not comparable due to changes in company reporting practices.

Bayer AG

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 16 SCORE 2.79

Has an access-to-medicine strategy with board-level responsibility. Bayer has an access-to-medicine strategy with a business rationale. Bayer's access approach has as a key focus on family planning and maternal and neonatal health. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Bayer 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 variable performance-related compensations. Bayer's senior management has a separate incentive that supports the company's long-term access oriented objectives.

One of 16 companies working on impact measurement. Bayer measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, for example, it reports to commit to supply medicines to fight African sleeping sickness to WHO. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Bayer publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by a process based on expertise, activity and geographic coverage. Local stakeholder perspectives are incorporated into the development of its access strategies. It publicly shares its policy for ensuring responsible engagement; namely with its principles of responsible lobbying.

MARKET INFLUENCE & COMPLIANCE

RANK 10 SCORE 2.61

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Bayer has a policy relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. 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. Bayer's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it audits compliance following an annual audit plan. It does not report conducting fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system in place to track compliance in the workplace. However, Bayer does not demonstrate evidence of having procedures to segregate duties, so that decisions are checked by another party.

Average transparency regarding access-related practices. Bayer publicly discloses its policy positions on access-related topics (e.g., its positions on intellectual property, and TRIPS). It also publicly discloses political contributions in countries in scope. Bayer publicly discloses its memberships of relevant organisations to access in countries in scope, but not the financial contributions it provides. It discloses its policies for responsible engagement within its code of conduct. However, the company does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 8 SCORE 2.14

PROJECTS: 11 IN CLINICAL DEVELOPMENT: 9

Commits to R&D to meet public health needs. Bayer has made a specific commitment to R&D for diseases and countries in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on goals published by external sources like WHO. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Bayer has one of the smallest pipelines in the Index with 11 projects. For diseases in scope where priorities exist, Bayer is active in four projects; three of these target priority R&D gaps.

Access provisions in place for 11% (1/9) of late-stage candidates. Bayer does not have a clear process in place to develop access plans during R&D. It does, however, consider access for some R&D projects for diseases in scope, namely for collaborative projects. To date, Bayer has project-specific access provisions in place for one

of its late-stage R&D projects. This project, to develop a paediatric formulation of nifurtimox (Lampit®) for the treatment of Chagas disease, is being conducted in-house and includes a registration strategy and plan to apply for WHO prequalification.

No policy for post-trial access. Bayer 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 15 SCORE 2.07

PRODUCTS: 26

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 2

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

Many new products in scope filed for registration in the majority of relevant priority countries. Bayer has filed 70% 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). However, it does not publicly share registration information for any of its products.

12% of products have equitable pricing strategies targeting priority countries. Bayer's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 12% of its products for diseases in scope. These strategies apply to an average of 9% of priority countries. One of these strategies applies inter-country pricing; this strategy, for contraceptive methods, takes into account one socio-economic factor. Bayer also applies an equitable pricing strategy to one further product informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Bayer has guidelines for drug recalls 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 18 SCORE 0.33

Does not publicly disclose patent statuses.

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

No use of non-assert or licensing arrangements.

Bayer does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements.

Bayer reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi). 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.

No public commitment not to enforce patents in countries in scope. Bayer does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

CAPACITY BUILDING

RANK 14 SCORE 1.22

Six initiatives included for evaluation. Bayer has six 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; Bayer submitted 21.

Focused on supporting pharmacovigilance systems. Bayer has initiatives which meet inclusion criteria in two areas of capacity building: pharmacovigilance and health system strengthening. Most of these initiatives are focused on pharmacovigilance capacity building in sub-Saharan Africa.

Some initiatives meet some good practice standards. None of Bayer's included initiatives meet all the good practice standards looked for by the Index. Most of its initiatives have goals in place, but it commonly falls short on monitoring progress and outcomes.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Bayer has a policy for

reporting cases of substandard or falsified medicines to local regulatory authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 8 SCORE 3.33

STRUCTURED DONATION PROGRAMMES: 3

Responds to emergencies and humanitarian crises and tracks delivery. Bayer donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to the 2017 Mexico earthquake. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works, for example, with Direct Relief and Health Partners International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Bayer's programmes are focused on neglected tropical diseases (NTDs), namely Chagas disease and human African trypanosomiasis (HAT) of the type *T. b. gambiense* and *T. b. rhodesiense*. All three programmes are carried out in partnership with its long-term partner, WHO. Its NTD programme for Chagas disease supplies nifurtimox (Lampit®) in 14 countries in scope and has been ongoing since 2004. During the period of analysis, Bayer reports that this has reached almost 8000 patients.

Addresses longer-term needs by committing to eliminate disease. Bayer's structured donation programmes aim to eliminate the diseases targeted. For example, its nifurtimox (Lampit®) donation programme aims to support control and elimination of Chagas disease in 14 countries in scope. For its three neglected tropical diseases programmes, Bayer commits to supplying the drug as long as WHO requires it; i.e., until elimination of the disease.

BEST PRACTICES

Continued commitment to combat NTDs

GLOBAL

One of five companies running donation programmes to eliminate or eradicate NTDs.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.