PERFORMANCE IN THE 2021 INDEX

13th place. Bayer has an average performance. It delivers a strong approach to filing its new products for registration, but has a small-sized R&D priority pipeline and no structured process for access planning. Its approach to governance and compliance is average.

Governance of Access: 8th place. Bayer has an average performance in this area. It implements an access-to-medicine strategy with a business rationale and discloses outcomes of some of its access-to-medicine activities. The company has some compliance controls in place, but lacks evidence of a continuous system to monitor compliance across its activities.

Research & Development: 17th place. Bayer falls to the lower ranks in R&D. The company features a small-sized R&D priority pipeline compared to peers and does not have a structured approach to develop access plans during R&D. A few of its late-stage R&D projects are covered by access plans.

Expand access to more products. Bayer offers certain contraceptives for procurement through UNFPA for eligible countries and offers the same terms and price to non-eligible countries for ethinylestradiol/levonorgestrel/ferrous fumerate (Microgynon® ED Fe/Microgynon® Fe). Bayer can apply the same strategy in non-eligible countries for norethisterone enantate (Noristerat®). Furthermore, Bayer can apply equitable pricing strategies for contraceptives that are not procured through UNFPA: drosperinone/ethinylestradiol (Yasmin®), Estradiol valerate/diengost (Qlaira®/Natazia®) or estradiol valerate/norethisterone enantate (Norigynon®), specifically in countries with a low contraceptive prevalence rate such as Angola, Gambia, Guinea and Mauritania. Outside contraceptives, Bayer can expand affordable access to on patent EML products such as rivaroxaban (Xarelto®) for the prevention of stroke.

Develop an access planning process and access plans for all R&D projects. Bayer can develop a formal access planning process and accordingly develop access plans for all Phase II projects, such as levonorgestrel/indomethacin (a combination intrauterine device). Bayer can also further strengthen its recently updated post-trial access policy by committing to filing the product for registration in countries where clinical trials take place, while ensuring affordability.

Commit to donating until NTD elimination and control goals. In partnership with the WHO since 2002, Bayer has worked to eliminate African Sleeping Sickness (HAT) and to control Chagas disease in Latin America by donating suramin (Germanin®) and nifurtimox (Lampit®) until 2021. Bayer can extend its public commitment indefinitely until elimination of HAT and control of Chagas disease in Latin America.

PRODUCTS IN THE 2021 INDEX

How score was achieved

Governance of Access 3.55
Research & Development 1.01
Product Delivery 3.03

Bayer AG

Stock Exchange: Frankfurt Stock Exchange • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 103,824

OPPORTUNITIES FOR BAYER

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CHANGE SINCE THE 2018 INDEX

• Created a new external sustainability council to contribute to Bayer innovation, mindset and strategy as from May 2020.
• Disclosed a new commitment not to enforce or file for patents in all LICs.
• Joined Pat-INFORMED, publishing patent statuses for products in their portfolio.
• Supports the clinical development of novel antibiotics via the AMR Action Fund.
• Joined the COVID-19 Therapeutics Accelerator.
• Started a new two-year partnership in January 2020 with Living Goods to train Community Health Workers on family planning and neonatal care in rural Uganda.
• Established a new partnership with PATH for malaria and COVID-19 in Southern Senegal.
• Newly partnered with the UN Foundation for malaria eradication by donating Fludora® Fusion for vector control in Haiti.
• Has a new collaboration with John Hopkins University for The Challenge Initiative platform to enable governments in countries in scope of the Index to scale up family planning approaches for poorer populations in urban areas.
SALES AND OPERATIONS

Business segments: Crop Science; Pharmaceuticals; Consumer Health
Therapeutic areas: Cancer; Cardiovascular and kidney diseases; Eye conditions; Haemophilia; Contraception
Product categories: Innovative medicines
M&A news: Divested Bayer Animal Health to Elanco in August 2019 for USD 76 billion; acquired BlueRock (neurology) and Century (oncology) in 2019; announced acquisition of KaNDy Therapeutics (women’s healthcare) and of Asklepios BioPharmaceutical (gene therapies) in 2020.

Bayer Pharma’s products are sold in 92 out of 106 countries in scope. Bayer Pharma has sales offices in 37 countries, sells via suppliers in 7 countries and via pooled procurement into 48 additional countries.

Net sales by segment (2019) – EUR
- Crop Science: 19,832 bn
- Pharmaceuticals: 17,962 bn
- Consumer Health: 5,462 bn
- Reconciliation: 0.289 bn
- Total: 43,545 bn

Sales in countries in scope

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope
Bayer has a total of 42 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 7 projects. The other 35 R&D projects target other diseases in scope. Of the projects targeting priority diseases the focus is on Chagas disease (2 projects). Of the projects targeting other diseases in scope the focus is on oncology (18).
17 R&D projects are in late-stage development that target either a priority disease (6) or address a public health need in LMICs (11). Evidence of access planning was in place for 24% of these projects: 3 targeting a priority disease and 1 addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index
Bayer has 21 medicines and contraceptives in scope, 11 of which are on patent. 67% of these medicines and contraceptives (14) are on WHO’s EML. In addition, the company markets 12 vector control products. The off-patent medicines target mainly neglected tropical diseases (NTD), such as schistosomiasis, Chagas and Human African Trypanosomiasis. One medicine targets malaria. The on-patent medicines mainly target non-communicable diseases, such as oncology (5), cardiovascular disease and endometriosis. Additionally, one medicine targets bacterial infections. Bayer has eight contraceptives in scope. The vector control products target malaria, dengue, Chikungunya and Zika. Access strategies were analysed for 11 products on Bayer’s portfolio – supranationally procured (4) or nationally procured HCP-administered (2) and self-administered products (5).

42 projects in the pipeline

33 products as selected for analysis by the Index*

Breakdown of projects*

Levonorgestrel/indomethacin releasing intrauterine system for contraception.

Breakdown of products
Bayer AG

GOVERNANCE OF ACCESS

Has an access-to-medicine strategy with measurable objectives and a business rationale. Bayer has an average performance. It has an access strategy aiming at increasing the societal impact of their business activities. The strategy covers some 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. Provides evidence of financial and non-financial access-related incentives at the executive level. Bayer performs strongly in this area. 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 a subset of its access-to-medicine activities. Bayer performs well in transparency regarding access activities. It publicly discloses its 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 through the IFFPA Global Health Progress platform. Has an average performance in responsible promotional practices. Bayer’s sales agents are not solely incentivised on sales volume targets. Bayer sets sales incentives at the individual level for agents. Except for Ukraine where it discloses to EFPPIA, 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 approach limiting such transfers. Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Bayer has an average performance, demonstrating some of the components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes in place to ensure third-party compliance with company standards. It does not, however, have a continuous system to monitor activities. Publicly supports the Doha Declaration on TRIPS and Public Health. Bayer publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions; that is, compulsory licenses are considered a last resort. It states that it can dissent from industry association positions on IP.

RESEARCH & DEVELOPMENT

No structured process for access planning reported. Bayer does not have a structured process in place to develop access plans during R&D. The company does not have a structured timeline for the development of access plans for its R&D projects. A small-sized priority R&D pipeline compared to peers, with access plans in place for 50% of the late-stage candidates. Bayer has seven projects, including six late-stage candidates, in its pipeline that target a priority product gap. The company focuses mostly on Chagas disease. Of Bayer’s six late-stage candidates targeting a priority product gap, there is evidence of an access plan for three. These plans range from registration to a partnership with DNDi. A notable example is the paediatric rifampicin (Lampit®). Registration in additional endemic high disease-burden countries is planned for this project. Many projects address a public health need in LMICs, with one of the late-stage projects covered by access plans. In this analysis, Bayer has 11 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 concern clinical trials in countries in scope. Bayer provides access plans for one of these projects, which is darolutamide (Nubeqa®), indicated for prostate cancer. Registration in LMICs with subsequent access plans are planned.

PRODUCT DELIVERY

Public commitment not to enforce patents in countries in scope. Bayer publicly pledges to neither file for nor enforce patents. This commitment applies in low-income countries. Publicly discloses detailed information on patent status. Like most of its peers, Bayer discloses the patent statuses for small molecules in scope via the PATINFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction. Shares few IP assets with third-party researchers. Bayer has newly shared two IP assets with third-party researchers developing products for diseases in scope. It shares the assets with the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard, as well as with the Medicines for Malaria Venture (MMV). Assets shared include molecule libraries. No use of non-assert or licensing arrangements. Bayer does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope. Filed to register the majority of its new products in the majority of high burden countries. Bayer has filed 65% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, the oncology medicine regorafenib (Stivarga®) has been filed for registration/registered in seven high burden countries in scope. Has access strategies for some supranationally procured products in scope of this analysis. Bayer has average performance in securing access for products procured supranationally. For three of the four products assessed in this category, it demonstrated strategies both in countries eligible for supply from such procurers and also in at least one country not eligible for such supply. For example, the company offers the same terms in Iraq for the oral con-
practice pill; Microgynon® ED Fe; as they do in UNFPA-eligible countries. For the remaining products there was no evidence of equitable pricing strategies in non-eligible countries.

Has access strategies for the healthcare practitioner-administered products in scope of this analysis. Bayer performs below average in this area. It provides weak examples of access strategies which consider affordability in countries of all assessed income levels (LMIC, LRIC, LIC) for one of the two products assessed. The company makes efforts to reach additional patients through donations. For example, in Brazil, it donated 33,000 contraceptive LNG IUS implants to increase access, while strengthening the health system via healthcare practitioner trainings. Bayer 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 for this analysis. Bayer has average performance in this area. It shows some strength in access strategies in UMICs, though not in LMICs and LICs. The company applies access strategies which consider ability to pay/affordability for UMICs in three out of the five products assessed. It makes efforts to reach additional patients through equitable pricing strategies. For example, in China, they reduced the price of sorafenib (Nexavar®) and regorafenib (Stivarga®), two oncology medicines, to be listed on the reimbursement list and increase access for patient. After sorafenib was listed for reimbursement, the patient number increased from 8,000 in 2017 to about 19,000 in 2019. Bayer is able to provide evidence of how patient reach has been increased through the approaches used.

One manufacturing capacity building initiative included for evaluation. Bayer performs below average in this indicator. Bayer submitted two initiatives. One initiative, supporting Contract Manufacturing Organisations in addressing PSCI and Environment, Health and Safety gaps, met all criteria for inclusion but not all Good Practice Standards. Bayer did not sufficiently demonstrate how the initiative aims for sustainability and is measuring outcomes.

Two supply chain capacity building initiative meet all Good Practice Standards. Bayer performs average on this indicator. Bayer submitted four initiatives, of which two initiatives met all criteria for inclusion and all Good Practice Standards. Bayer did not sufficiently demonstrate how the initiative aims for sustainability and is measuring outcomes.

Two health system strengthening initiatives meet all Good Practice Standards. Bayer performs average in this indicator, with four health system strengthening initiatives that met all criteria for inclusion: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives and (plan to) measure outcomes. Two initiatives met all Good Practice Standards, including an NCD care programme in Ghana and The Challenge Initiative, which enables governments to scale up high-impact family planning approaches. For Bayer’s other two initiatives, a partnership with PATH to eliminate malaria and fight COVID-19 in Senegal and a partnership with Living Goods in Uganda to train community health workers on family planning and neonatal care, Bayer did not provide sufficient evidence on having a good governance structure in place.

Has engaged in the development and implementation of new inclusive business models. Compared to peers, Bayer performs well 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 newly developed four models: iBreast exam on breast cancer, partnership with BISA on digital health, partnership with Access Afya on the COVID-19 response, M UNITY® (mPharma) on cardiovascular diseases.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Bayer performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. In addition to multiple processes to align demand forecasting and supply, Bayer has a ‘stockout situation notification procedure’ in case of temporary shortage, which covers all products in its portfolio. During supply shortages, Bayer reports implementing the fair share principle, prioritising supply on the basis of medical needs status and ensuring that supply commitments to Global Healthcare Programmes are prioritised over commercial products. Bayer reported implementing this process in 2019 for two contraceptives, oral levonorgestrel/ ethinylestradiol (Microgynon®) and injectable norethisterone enantate (Noristerat®), ensuring supply through USAID and/or the UNFPA.

Has a policy for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. Bayer performs well here. It has a policy for reporting SF medicines to national health authorities within 7 days for the most severe risk category. It does not distinguish reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need and monitors delivery to end users. Bayer has a policy in place to ensure ad hoc donations are carried out only in response to an expressed need and it monitors the delivery until the end user. For example, it donated chloroquine (Resochin®) to 27 countries in 2020 in response to the COVID-19 pandemic.

Publicly commits itself to achieving 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. Bayer publicly commits itself to controlling Chagas disease and eliminating Human African Trypanosomiasis by donating nifurtimox (Lampit®) and suramin (Germirgin®) from 2002 to 2021.