

RANK	SCORE
2 [▲]	3.21
3 (2016)	

Novartis AG

Stock Exchange: SIX Swiss Exchange • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 126,457

PERFORMANCE

Rises 1 place to 2nd position. The company has launched a new approach to access, embodied by the Novartis Access Principles, which aims to expand access planning across the company's pipeline.

Management: Holds 1st place. Refreshed access strategy underpinned by the Novartis Access Principles, with CEO remuneration linked to access performance.

Compliance: Rises 13 places to 2nd. Improved performance compared to peers in its internal controls and transparency, including financial support made to patient groups.

R&D: Rises to 3rd place for its new approach to considering access planning for all new medicines.

Pricing: Holds 3rd place, with an above-average performance across all pricing metrics but outperformed by leaders.

Patents: Falls 6 places to 16th. Despite a greater level of transparency around its patents, it falls due to an incident regarding the IP around imatinib (Glivec®) in Colombia.

Capacity: Falls 2 places to 3rd, but holds strong against new metrics for good practice, notably in health system strengthening.

Donations: Rises two places to 3rd, achieving a comparatively wide geographic coverage for its leprosy programmes which aim to eliminate the disease in 49 countries.

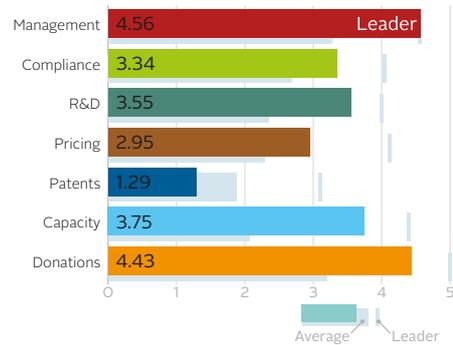
OPPORTUNITIES

Apply Novartis Access Principles to increase access across its entire late-stage pipeline. Novartis can work to ensure that its Access Principles are successfully applied to establish access plans for all new medicines in late-stage development regardless of disease scope. As the Novartis Access Principles were recently implemented in 2018, early success is critical to proving that access can be considered across the pipeline and successfully executed.

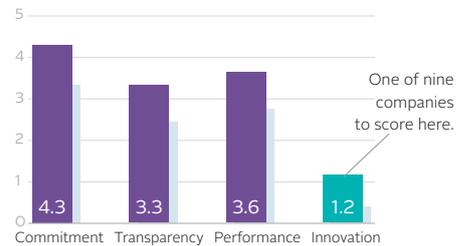
Expand equitable pricing strategies to cover all priority countries. Novartis' nilotinib (Tasigna®) for the treatment of cancer (leukaemia), is an on-patent product on the 2017 WHO Model List of Essential Medicines (WHO EML) and a first-line treatment. While equitable pricing strategies apply in some priority countries, the company could expand its scope to include all countries where need is the highest, including Egypt, Arab Rep., Kosovo, Kiribati, Micronesia, Fed. Sts., São Tomé and Príncipe and Tonga. Novartis has developed a new tool, Potential Affordability by Decile, to determine price segmentation in countries in scope. Novartis could apply this tool to address the affordability of products including valsartan (Diovan®) for hypertensive heart disease and ischaemic heart disease in low- and middle-income countries.

Expand access to more manufacturers through voluntary licensing. Novartis can actively identify generic medicine manufacturing partners for the non-exclusive voluntary licensing of products for high-burden diseases. Possible products could include nilotinib (Tasigna®) listed on the WHO EML for imatinib-resistant chronic myeloid leukaemia.

Performance by technical area



Performance by strategic pillar



CHANGE SINCE 2016

- Established Novartis Access Principles to systematically integrate access strategies for all new products and Sandoz biosimilar launches beginning as early as Phase II.
- Reiterated its commitment to the control of non-communicable diseases with the Novartis Access Programme, expanding to new countries, such as Pakistan.
- Adapted the SMS for Life platform for stock management; the new, enhanced SMS for Life 2.0 has been launched in four countries since mid-2016.
- Launched the Better Hearts Better Cities initiative in May 2017 to improve cardiovascular health in low-income urban populations.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Published its expanded post-trial access policy to provide access to investigatory treatments for clinical trial participants that meet certain criteria after trials have concluded.
- Divests antibacterial and antiviral research.

PIPELINE for diseases and countries in scope

Comparatively large pipeline: 117 R&D projects (all medicines) for diseases in scope.

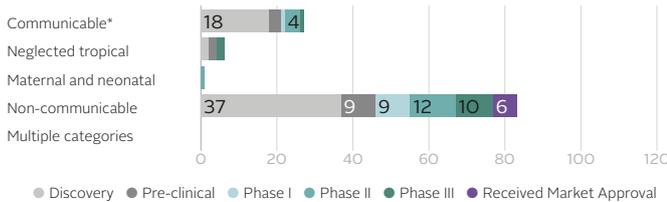
Clinical candidates: 40, including three clinical candidates for the treatment of *Plasmodium falciparum* malaria.

Regulatory approvals: 6, erenumab (Aimovig™), a novel once-monthly self-injection for the prevention of migraines.

R&D focus: non-communicable diseases (cancer and COPD) and communicable diseases (malaria).

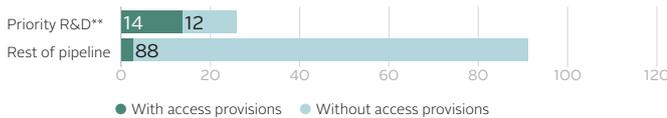
Access provisions: for 17 projects, most commonly registration and equitable pricing strategies.

Projects in the pipeline: 117



Triclabendazole (Egaten®) is approved in France for fascioliasis treatment, and Novartis is seeking approvals from additional health authorities. Novartis currently donates this product to WHO for use in endemic countries.

Projects for R&D priority targets with access provisions: 14



Of Novartis' 117 R&D projects, 17 are supported by access provisions: e.g., nilotinib (Tasigna®) has donation programmes available for chronic myeloid leukaemia patients in several countries in scope through the Max Foundation. Nine of its 36 late-stage projects have provisions.

BUSINESS CONTEXT

Three divisions: Innovative Medicines; Alcon; and Sandoz (generic medicines and biosimilars). Its Innovative Medicines division has two business units: Novartis Pharmaceuticals; and Novartis Oncology. Novartis Pharmaceuticals unit focuses on six therapeutic areas: ophthalmology; immunology; dermatology; neuroscience; respiratory; and cardiometabolic diseases. Novartis Oncology focuses on two therapeutic areas: cancers and rare diseases.

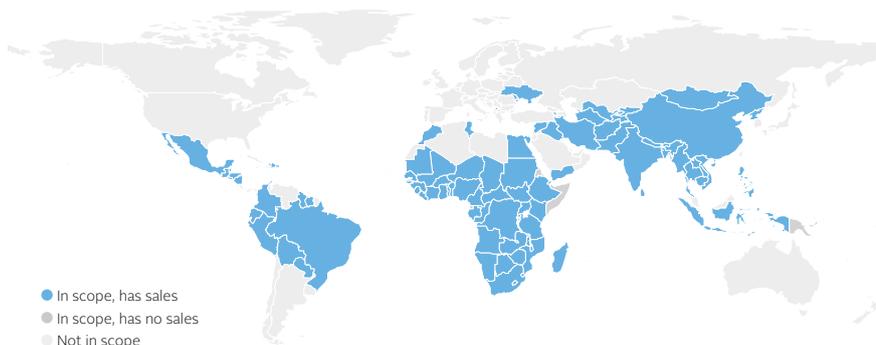
M&A news: 2018 sale of 36.5% stake in consumer healthcare joint venture to GSK. 2018 acquisition of cancer drugmaker Endocyte.

Presence in emerging markets: In 2018, Novartis reports sales in 95 countries in scope; 18 more countries than in the 2016 Index. It is the company with sales in the highest number of countries in scope. It reports that just over 20% of its sales in 2017 came from the Asia, Africa and Australia region.

Net sales by segment (2017) - USD

Innovative Medicines	33,025 MN
Sandoz	10,060 MN
Alcon	6,024 MN
Total	49,109 MN

Sales in countries in scope



Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
 **See Appendix IV for definition.

PORTFOLIO for diseases and countries in scope

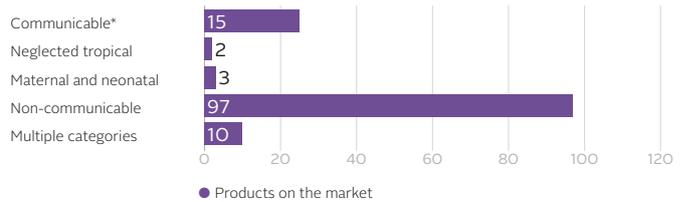
Largest portfolio: 127 products for diseases in scope (126 medicines; 1 contraceptive method).

Portfolio focus: non-communicable diseases (hypertensive heart disease and cancer) and communicable diseases (lower respiratory infections).

Essential medicines: 72% of Novartis' medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

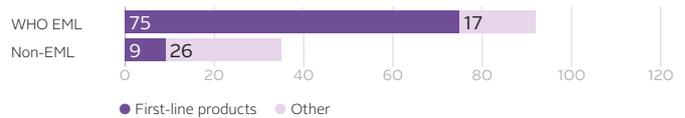
First-line treatments: 66% of Novartis' medicines have first-line indications for diseases in scope.

Products on the market: 127



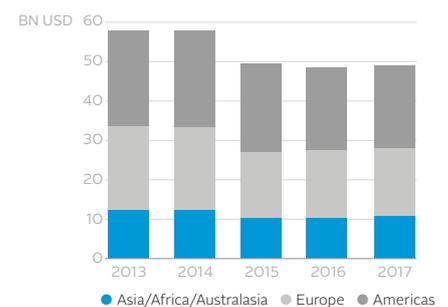
Novartis' portfolio includes products such as clofazimine/dapsone/rifampicin (MDT-Combi) for the treatment of multibacillary leprosy and sacubitril/valsartan (Entresto®) for the treatment of ischaemic heart disease.

Essential medicines with first-line indications: 75



80% of Novartis' medicines are listed on the WHO EML and/or as first-line treatments: e.g., the anticancer agents imatinib (Glivec®), anastrozole, tamoxifen and cisplatin.

Net sales by geographic region



Novartis AG

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 1 SCORE 4.56

Has a strong access-to-medicine strategy with board-level responsibility. Novartis is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy has three objectives focused on low-income markets: the control and elimination of disease; piloting new business approaches and engaging in R&D for unmet needs. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Novartis 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. Non-financial incentives include a global programme recognising associates making significant contributions towards corporate responsibility initiatives. Senior management achievement of access objectives is linked to compensation.

One of 16 companies working on impact measurement. Novartis measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments, objectives, targets and performance information. For example, for its Malaria Initiative, Novartis reports having provided more than 850 million treatments on a non-profit basis, to more than 60 countries since 2001, contributing to a significant reduction of malaria-related deaths. Furthermore, it is one of the companies that is measuring impact, with Boston University Metrics Framework, for at least one access initiative, e.g. Novartis Access.

Clear and transparent engagement approach that includes local stakeholders. Novartis 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 conducting a corporate responsibility materiality analysis, including research and surveys with internal and external stakeholders. Local stakeholder perspectives are incorporated into the development of its access strategies. It has some policies covering responsible interactions with stakeholders; namely on prioritising access

to healthcare, innovation, patient health and safety, and ethical business practices.

MARKET INFLUENCE & COMPLIANCE

RANK 2 SCORE 3.34

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Novartis has a code of conduct 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. Sales agents' rewards are not solely based on sales targets. Instead, Novartis newly rewards other aspects such as performance, innovation, collaboration, courage and integrity.

Internal control framework meets all Index criteria. Novartis has all the components looked for by the Index for an effective internal control framework to ensure compliance. Namely, it reports that it regularly conducts fraud-specific risk assessments. It has a global risk assessment, and a monitoring system to track compliance. It also has an auditing and review mechanism in place, which apply to third parties. Novartis demonstrates evidence of having procedures to segregate duties, so that decisions are checked by another party.

Above average transparency regarding access-related practices. Novartis publicly discloses its policy positions on access-related topics (e.g., its perspective on corporate responsibility including quality and safety of medicines, intellectual property, and its Access to Healthcare Perspective). The company discloses political contributions in countries in scope. It discloses its membership of relevant institutions and whether it provides financial support. Novartis discloses its policy for responsible engagement through its global policies for Responsible Lobbying and Anti-Bribery; its policies also include access perspective, intellectual property and quality and safety. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 3 SCORE 3.55

PROJECTS: 117 IN CLINICAL DEVELOPMENT: 40

Publicly commits to R&D to meet public health needs. Novartis has publicly committed to R&D

for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Novartis has one of the largest pipelines in the Index with 117 projects. For diseases in scope where priorities exist, Novartis is active in 28 projects; 26 target priority R&D gaps.

Access provisions in place for 25% (9/36) of late-stage candidates. Novartis has a clear process in place to develop access plans during R&D through its Novartis Access Principles. This process considers all R&D projects for diseases in scope. In general, Novartis develops access plans for R&D projects in Phase II of clinical development. To date, Novartis has project-specific access provisions in place for nine of its late-stage R&D projects. Of these, four are being conducted in partnership.

Public policy to ensure post-trial access; commits to registering trialed products. Novartis has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Novartis commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 3 SCORE 2.95

PRODUCTS: 127

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 72

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Novartis does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implementing equitable pricing strategies for the majority of its products for diseases in scope.

Many new products in scope filed for registration in the majority of relevant priority countries. Novartis has filed 50% of its newest products for registration to date in more than half of

the 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.

57% of products have equitable pricing strategies targeting priority countries. Novartis' overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 57% of its products for diseases in scope. These strategies apply to an average of 20% of priority countries. Almost all of these strategies apply inter- and intra-country pricing; these take into account an average of six and one socioeconomic factors, respectively. Novartis also applies equitable pricing strategies to three further products informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Novartis 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 16 SCORE 1.29

Publicly discloses detailed information on patent statuses. Like most of its peers, Novartis publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Novartis does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Shares few IP assets with 3rd-party researchers. Novartis shares one IP asset with third-party researchers developing products for diseases in scope. It shares this asset with the University of Cape Town. The assets shared include a molecule library.

Public commitment not to enforce patents in countries in scope. Novartis commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries.

CAPACITY BUILDING

RANK 3 SCORE 3.75

22 initiatives included for evaluation. Novartis has 22 capacity building initiatives that were included for analysis by the Index: i.e., the initia-

tives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Novartis submitted the maximum.

Strong focus on strengthening capacity of local R&D, manufacturing and health systems. Novartis has initiatives which meet inclusion criteria in all five areas of capacity building. It has at least one initiative in all areas which meet all good practice standards, except pharmacovigilance capacity building. Novartis performs strongest in manufacturing capacity building, R&D capacity building and health system strengthening.

12 initiatives meet all applicable good practice standards:

- Bangladesh alternative distributor project
- Novartis Malaria Initiative
- Better Hearts Better Cities
- Partnerships to develop capabilities in oncology
- Novartis Foundation Leprosy Initiative (LEARNS & LPEP)

A full list of Novartis's capacity building initiatives which meet all good practice standards can be found online.

Novartis's remaining included initiatives typically fall short on just one good practice standard. For example, two of its pharmacovigilance initiatives did not show evidence of good governance structures and process for mitigating conflicts of interest.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe.* Novartis has a policy of reporting cases of substandard or falsified medicines to relevant authorities and in some cases to WHO Rapid Alert. For example, Novartis reported a case of falsified arthemeter/lumefantrine (Coartem®) to WHO Rapid Alert in the period of analysis. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 3 SCORE 4.43

STRUCTURED DONATION PROGRAMMES: 3

Responds to emergencies and humanitarian crises and tracks delivery. Novartis donated medicines on the request of relief agencies. For example, during the period of analysis, it donated medicines in response to Hurricane Harvey in Haiti in 2017. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with the Swiss Red Cross and the International Committee of the Red Cross to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering dis-

eases and countries in scope. Novartis' programmes are focused on neglected tropical diseases (NTDs) and non-communicable diseases. All three programmes are carried out in collaboration with partners such as WHO and the Max Foundation. Its programme for chronic myeloid leukemia supplies imatinib (Glivec®) and nilotinib (Tasigna®) in 57 countries and has been ongoing since 2002. Novartis reports that almost 71,000 patients have been reached in Index Countries during the period of analysis.

Addresses long-term access by aiming to eliminate disease. Novartis commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its multi-drug therapy donation programme aims to eliminate leprosy in 49 countries.

BEST PRACTICES

Leading approach to measuring impact

A developed, tested and applied methodology for measuring impact on society in financial, environmental and social (FES) terms.

Three companies incorporate framework of strict guidelines to reduce non-compliance

Astellas, GSK and Novartis stand out for their comprehensive internal control frameworks.

Makes detailed commitment to providing post-trial access, goes further than peers

Detailed policy for providing investigational products to all clinical trial participants until the product is commercially available.

R&D unit dedicated to adaptive R&D aims to improve efficacy, safety and access

Unique R&D unit dedicated to adapting existing medicines to meet the specific needs of people living in low- and middle-income countries.

SMS for Life 2.0 expands to further prevent stock-outs of medicines

Enhanced mobile technology supply chain management system, now utilising new technologies and expanding to more countries and products.

Going beyond philanthropy: strengthening care at community level

Over 10 years, it has run initiatives alongside government health ministries and local NGOs to tailor healthcare activities to local needs.

INNOVATIVE PRACTICES

Novartis Access Principles to establish access provisions during development

A systematic approach to developing access strategies for each new medicine during development.

Novartis Access uses portfolio approach to address affordability for NCD products

Portfolio of 15 products for non-communicable diseases marketed to national governments, NGOs and other stakeholders, for \$1 per treatment per month, supported by capacity building.

ComHIP enables patients to access diagnosis and care at community level

Public-private partnership that embeds services for hypertension control and self-management in local communities

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