

RANK	SCORE
2	4.18
2 (2018)	

Novartis AG

Stock Exchange: SIX Swiss Exchange • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 103,914

PERFORMANCE IN THE 2021 INDEX

2nd place. Novartis is a leading company. The company has a strong performance in all three Technical Areas of the Index, leading in its approach to Product Delivery.

Governance of Access: 2nd place. It has embedded access to medicine into its corporate strategy under the Novartis Access Principles. The company has access-related incentives for the CEO and a robust set of compliance controls.

Research & Development: 3rd place. Novartis performs strongly in this area. It has an access planning process in place that covers all projects in the pipeline. It is the only company that both commits to post-trial access to all clinical trial participants and considers post-trial affordability in countries in scope. The company has nine late-stage priority R&D projects in the pipeline, with two-thirds covered by comprehensive access plans.

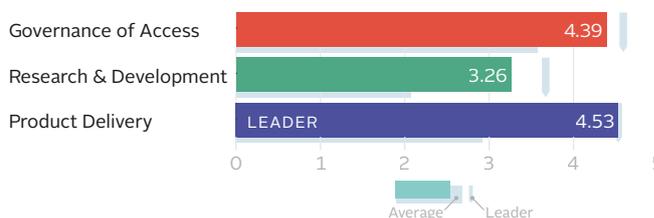
OPPORTUNITIES FOR NOVARTIS

Expand technology transfers to other geographic areas. Novartis reports three technology transfers to build manufacturing capacity, including one for biosimilars. Capacity building is focused on middle-income countries such as Brazil and Pakistan. The company can expand its technology transfer initiatives to low-income countries, including those in sub-Saharan Africa.

Implement an access planning process across all late-stage R&D projects. In its Novartis Access Principles, the company commits to planning for access for all late-stage R&D projects from Phase II onwards. The company can implement project-specific access and registration plans as well as access strategies addressing affordability for all late-stage R&D projects, e.g. for asthma and cancer.

Improve access to patented products on WHO EML. In the countries in scope, Novartis can further expand access to patented products listed on the 2019 WHO List of Essential Medicines such as nilotinib (Tasigna®) by increasing affordability and supply through voluntary licensing and equitable pricing strategies. Countries such as Vanuatu, Myanmar, Laos, Philippines, Ecuador, Bolivia, El Salvador, Ukraine can be considered.

How score was achieved



Product Delivery: 1st place. Novartis leads in this area. Leading consistently across access strategies, it is the only company that applies equitable access strategies in low-income countries (LICs) for all its products. It has newly shared thirteen IP assets and leads in this area. The company engages in all areas of capacity building and performs strongly in implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope.

CHANGE SINCE THE 2018 INDEX

- Launched new strategy to reach more patients in sub-Saharan Africa (SSA) across its portfolio.
- Newly commits itself to patient access targets in low- and middle-income countries, reinforced via sustainability-linked bond.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Partners with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four Pharmaceutical companies on Africa Health Worker Training Initiative
- Engages in new IP sharing via WIPO Research (TB, Chagas and malaria), the COVID-19 Therapeutics Accelerator, IMI call 21 project institutions, DNDi and MMV.
- Started Afya Dumu (End to End Care Model, Kenya) working with Kenya County governments to improve clinical outcomes in chronic diseases through community awareness, building capacity of healthcare providers, product access and improved supply chain management.
- Has new technology transfer agreements with Indian manufacturers for TB products and products falling under the Healthy Family programme and with Chinese manufacturer for Kymriah® for cancer.
- Partners with the government of Brazil on 10-year technology transfer of biosimilars with initial focus on rituximab.
- Collaborates with West African Centre for Cell Biology of Infectious Pathogens (WACCBIP) to improve research capabilities.

The term LMIC is used to denote all low- and middle-income countries in the 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.

SALES AND OPERATIONS

Business segments: Innovative Medicines; Sandoz
Therapeutic areas: Oncology; Ophthalmology; Neuroscience; Immunology, Hepatology and Dermatology; Respiratory; Cardiovascular, Renal and Metabolism; Anti-infectives (Sandoz)
Product categories: Innovative medicines; Generic medicines; Biosimilars
M&A news: In 2019, Novartis acquired The Medicines Company for USD 9.7 billion and the

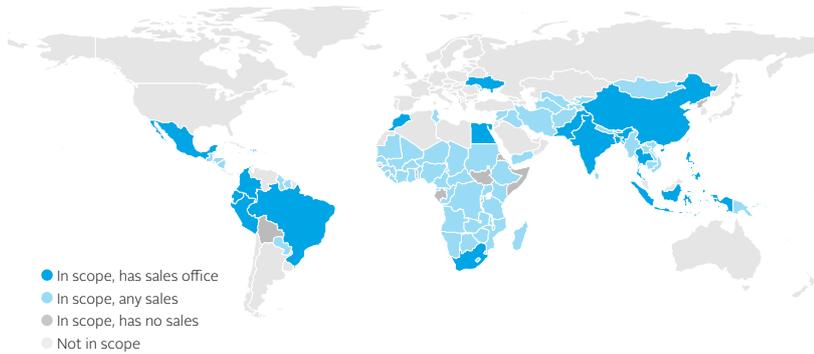
eye care business of Takeda for USD 3.4 billion. Spun off Alcon, its eye care business, in April 2019.

Novartis' products are sold in 83 out of 106 countries in scope. Novartis has sales offices in 16 countries, sells via suppliers in 57 countries and via pooled procurement in 10 additional countries.

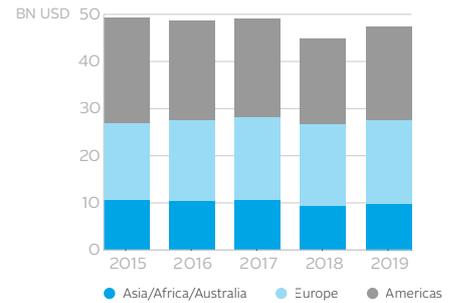
Net sales by segment (2019) – USD

Innovative Medicines	37.714 bn
Sandoz	9.731 bn
Total	47.445 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Novartis has a total of 60 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 21 projects. Remarkably, more than one third of the Novartis total R&D projects target priority diseases. The other 39 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (9 projects) and COVID-19 (5). Of the projects targeting other diseases in scope, the focus is on asthma (4) and oncology (23).

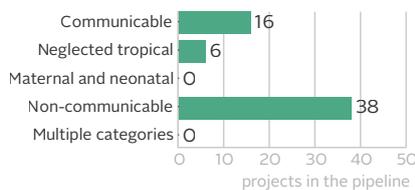
28 R&D projects are in late-stage development that target either a priority disease (9) or address a specific need in LMICs (19)*. Evidence of access planning was in place for 57% of these projects: 6 targeting a priority disease and 10 addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

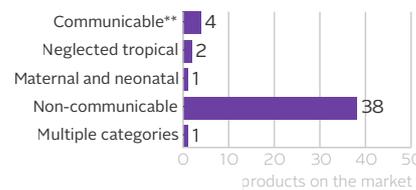
Novartis has 46 medicines in scope, 24 of which are on patent. 52% of these medicines (24) are on WHO's EML. The off-patent medicines target mainly non-communicable diseases (NCDs) (15) such as cardiovascular diseases (6) and cancer (3). Four products target communicable diseases such as tuberculosis (3) and malaria. Two further products target the neglected tropical diseases (NTDs) leprosy and food-borne trematodiasis. One further product targets maternal haemorrhage. The on-patent medicines mainly target NCDs such as cancer (11) and pulmonary diseases (4). One further medicine targets hepatitis B.

Access strategies were analysed for 13 products on the Novartis portfolio – supranationally procured (4) or nationally procured HCP-administered (4) and self-administered products (5).

60 projects in the pipeline



46 products as selected for analysis by the Index†



Breakdown of projects*

KAF156/lumefantrine is the first compound to progress into clinical development from the novel imidazolo-piperazine class of antimalarial molecules (partnership with MMV)

Crizanlizumab (Adakveo) a targeted therapy to treat patients with sickle cell disease.

	Pre-clinical	Phase 1	Phase 2	Phase 3	Approval	Total	W. access plans
Targets established R&D priorities	4	1	4	4	0	13	6
Addresses needs of LMICs*	0	11	13	5	2	31	10
Other projects in scope	0	7	1	0	0	8	

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	4	20			24
off patent	20	2			22
Vaccines	0	0			0
Diagnostics			0		0
Other				0	0

1 product for sickle cell disease

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, 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.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Novartis AG

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.39

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Novartis performs strongly. It has an access strategy embedded in the Novartis Access Principles and a new tailored approach for sub-Saharan Africa. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Governance, Nomination and Corporate Responsibilities Committee.

Provides evidence of financial and non-financial access-related incentives at executive level. Novartis 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 included in their performance targets.

Publicly discloses outcomes of its access-to-medicine

activities. Novartis performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, namely the progress of its Access Principles initiatives, in various channels e.g. its annual report.

Has an average performance in responsible promotional practices. Novartis' sales agents are not solely incentivised on sales volume targets. The company sets sales incentives at the individual level for agents. Except for Ukraine where it reports to EFPIA[†] and other cases where it is required by law, Novartis 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 limiting such transfers.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novartis performs strongly, demonstrating 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 third-party compliance with company standards.

Publicly supports the Doha Declaration on TRIPS and Public Health. Novartis publicly shares explicit support of the Doha Declaration on TRIPS and Public Health without expressing reservations on the appropriate use of its flexibilities, including compulsory licences, parallel imports, Bolar provisions, exemptions for Least Developed Countries (LDCs). It has a statement of independence to dissent from industry association positions on IP.

RESEARCH & DEVELOPMENT

RANK 3

SCORE 3.26

Access planning processes encompass all projects in pipeline. Novartis 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 for diseases in scope. In general, Novartis begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

An average-sized priority R&D pipeline compared to peers, with access plans in place for 67% of the late-stage candidates. Novartis has 21 projects, including nine late-stage candidates in its pipeline, that target a priority product gap. Of the projects targeting priority diseases, the focus is on malaria (9 projects) and COVID-19 (5). Of the Novartis nine late-stage candidates targeting a priority product gap, six have an access plan. These plans are mostly applied through access-oriented partnerships with PDPs and focus on affordability and availability.

Many projects address a public health need in LMICs*, with 53% of the late-stage projects covered by access plans. In this analysis, Novartis has 19 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 and/or are first-in-class molecules, e.g. for asthma. Novartis provides evidence of access plans for ten of these projects. These access strategies across the portfolio include commitments to register products in countries in scope and to strive to take equitable pricing strategies in to account for some projects (i.e. income levels, local affordability barriers). Notable, is Egaten® (triclabendazole) to control fascioliasis. This product will continue to be donated to more than 40 eligible countries through the WHO.

Public policy to ensure post-trial access; commits itself to registering trialed products. Novartis has a public policy for ensuring post-trial access to treatments for clinical trial participants. The policy covers all clinical trial participants. Once a product is approved, Novartis commits itself to registering it in all countries where clinical trials for the product have taken place. The policy considers affordability for the wider population in the country where the trial(s) took place.

One R&D capacity building initiative meets all Good Practice Standards. Performs above average in this indicator. Novartis submitted the maximum of five initiatives and four met all criteria for inclusion. One initiative, the Memorandum of Understanding (MoU) with the South African Department of Science and Technology (DST) and South African Medical Research Council (SAMRC), met all Good Practice Standards.[§] For Novartis' Scientific Exchange Programs, the company does not demonstrate how it aims for long-term impact on local R&D capacity.

PRODUCT DELIVERY

RANK 1

SCORE 4.53

Public commitment not to enforce patents in countries in scope. Novartis publicly pledges to neither file for nor enforce patents. This commitment applies in all Least Developed Countries, low-income countries and a subset of lower middle-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Novartis discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically

updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares many IP assets with third-party researchers. Compared to its peers, Novartis has newly shared many IP assets with third-party researchers developing products for diseases in scope. This includes thirteen IP assets shared with research institutions and drug discovery initiatives such as COVID-19 Therapeutics Accelerator launched

by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries.

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.

Filed to register some new products in the majority of

[†] Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare pro-

fessionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

[§] Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

high burden countries. Novartis has filed 10% 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, sacubitril/valsartan (Entresto®) for ischaemic heart disease has been filed for registration/registered in six high burden countries in scope, including Moldova and Morocco.

Has access strategies for all supranationally procured products in scope of this analysis. Novartis leads in securing access for products procured supranationally.[¶] For 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 non-eligible country. For example, the company offers the same terms in South Africa for the tuberculosis medicine Lamprone® as they do in Global Drug Facility eligible countries.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Novartis leads in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for three of the four products assessed. Novartis makes efforts to reach additional patients using equitable pricing strategies. For example, in India, for omalizumab (Xolair®), a treatment for asthma, the company uses tenders and launched an emerging market brand offered at discount price to increase access, while strengthening the health system by increasing affordability and accessibility to spirometry tests. Novartis is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for the majority of self-administered products in scope of this analysis. Novartis leads in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for the five products assessed. Novartis makes efforts to reach additional patients using both inter- and intra-country equitable pricing strategies. For example, in Uganda, part of the new sub-Saharan business model, the company offers different packs of vildagliptin depending on income level. For the top of the income pyramid, vildagliptin (Galvus®) and vildagliptin/metformin (Galvus-met®) are offered at a higher price. For the base of the pyramid and in the lower-income private market 'Novartis Access' Vildagliptin is offered at a lower price. 400 patients gained access to this treatment since 2019 in Uganda. Novartis is able to provide evidence of how patient reach has been increased through the approaches used.

Three manufacturing capacity building initiatives meet all Good Practice Standards. Novartis performs above average in this area. Novartis submitted the maximum of five initiatives, of which four met all criteria for inclusion. Three initiatives, technology transfers of a wide range of products India, Iran and Pakistan and biosimilars in Brazil, met all Good Practice Standards.[¶]

Three supply chain capacity building initiatives meet all Good Practice Standards. Novartis performs well in this area. Novartis submitted the maximum of five initiatives and all met all criteria for inclusion. Three initiatives met all Good Practice Standards.[¶] Examples include:
- Authentifield by Novartis, enabling mobile and fast detec-

tion of counterfeit medicines in 12 countries in scope of the Index.

- Drone delivery partnerships with Zipline and Linex in Ghana and Brazil, respectively, enabling faster supply to harder-to-reach areas. In Ghana, Zipline reaches 12 million people across the country.

For the two other initiatives, which include demand and supply planning with the WHO for donated leprosy medicine and workshops on standardised supply chain processes for distribution partners in sub-Saharan Africa, Novartis did not sufficiently demonstrate how they aim for sustainability.

Four health system strengthening initiatives meet all Good Practice Standards. Novartis is one of the leading companies. The company submitted the maximum of five initiatives and all met all criteria for inclusion and all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, through the Afya Dumu /'End to End Care Model', Novartis aims to screen 200,000 people and improve clinical outcomes for cancer and diabetes through early diagnosis, early treatment and proper follow-up.

Has engaged in the development and implementation of new and scaled up inclusive business models. Novartis performs strongly 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 scaled up its models Novartis Access on non-communicable disease (NCD) care and Healthy Family creating health camps and contributed to one new: the Novartis Africa Sickle Cell Disease Flagship programme.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Novartis performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. The Novartis process to align demand and supply is applied globally in countries where Novartis has an affiliate of distributor, including in 31 Least Developed Countries. The Novartis Supply Risk Management framework is regularly reviewed and updated, which can be followed by measures such as increased safety stocks, pandemic preparedness plans and the implementation of dual API sourcing strategies.

Has a policy for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. Novartis has a policy for reporting SF medicines to both national health authorities and WHO, within 7 days. Novartis authentication relies on packaging data verification, packaging testing (i.e. security features) and/or product testing whichever can be performed the fastest. The policy classifies incidents following categories according to their degree of severity, which may enable faster action.

Donates in response to an expressed need, but does not monitor delivery to end user. Novartis has a policy in place to ensure ad hoc donations are carried out in response to an expressed need; however, it does not monitor the delivery until the end user.

Publicly commits to the achievement of elimination,

eradication or control goals in its structured donation programmes for NTDs. Two structured donation programmes for NTDs were included for analysis where elimination, eradication or control goals are possible. In one programme, Novartis publicly commits itself to eliminating leprosy by donating the MDT Combi clofazimine/dapsone/rifampicine (Lamprone®/Rimactane®/Dapsone®) from 2000 to 2020 in 74 countries. Moreover, it is engaged in another structured donation programme: the Max Access Solution programme whereby it has been donating imatinib (Glivec®) and nilotinib (Tasigna®) for leukaemia and gastrointestinal stromal tumours in 33 countries since 2002.

¶ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

¶ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.