

RANK	SCORE
<b>4</b>	<b>3.87</b>
2 (2021)	

# Novartis AG

Stock exchange: SWX • Ticker: NOVN • HQ: Basel, Switzerland • Employees: ~108,000

## PERFORMANCE IN THE 2022 INDEX

4<sup>th</sup> place. Novartis ranks among the top five companies in the Index. Novartis has comprehensive access plans in place for all late-stage candidates in the pipeline and performs strongly in high-quality capacity building initiatives across all fields. The company leads in its approach to access strategies for self-administered products.

**Governance of Access:** 15<sup>th</sup> place. Novartis performs below average in this area. It has integrated access-to-medicine into its corporate strategy under the Novartis Access Principles and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index. However, the company was found to be the subject of a legal settlement during the period of analysis based on conduct by a former subsidiary.

**Research & Development:** 3<sup>rd</sup> place. Novartis performs strongly in this area. It has an access planning framework and applies this to all its late-stage pipeline candidates. Novartis performs strongly in R&D capacity building and leads by publicly disclosing R&D investments for priority neglected diseases.

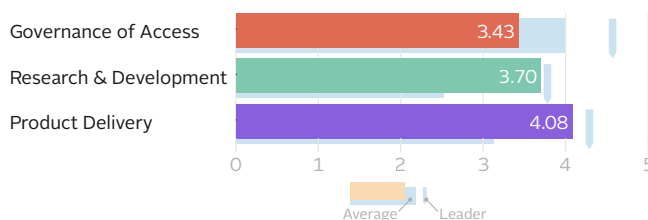
## OPPORTUNITIES FOR NOVARTIS

**Expand technology transfers to more countries.** Novartis reports seven technology transfers to build manufacturing capacity. Capacity building is focused on countries like China, India and Brazil which have well-established pharmaceutical markets. The company can engage in further technology transfers in countries where its products address a high disease burden, aiming to expand access and regional availability. For example, Novartis can transfer technology for its products indicated for chronic obstructive pulmonary disease or products in its oncology portfolio.

**Expand the geographic scope of the CancerPath to Care initiative.** In 2022, Novartis announced the expansion of its donation and capacity building efforts for cancer products beyond chronic myeloid leukaemia (CML) through partnership with The Max Foundation called CancerPath to Care. Novartis will continue to support the Foundation with the delivery of the donation treatments for breast cancer, CML and rare cancers. Novartis can work with partners to expand donations and capacity building efforts through this initiative to more countries with a high disease burden.

**Expand access to breast cancer and cardiovascular products.** Novartis has access strategies in place for its breast cancer product, ribociclib (Kisqali®), in at least one upper-middle income country and lower-middle income country, and has committed to implementing an access strategy in at least three low-income countries (LICs) in the future. Novartis can provide evidence of implementing additional access strategies for ribociclib in LICs. In addition, it can expand patient reach via non-pricing access strategies such as non-exclusive voluntary licences (NEVLs). For example, Novartis has announced a NEVL for nilotinib (Tasigna®), indicated for leukaemia. Novartis could also pursue a NEVL for ribociclib.

How score was achieved



**Product Delivery:** 4<sup>th</sup> place. Novartis performs strongly in this area. The company has high quality access strategies in place across all country income classifications for a subset of its products. It has scaled up and piloted the highest number of inclusive business models of all companies. It also performs strongly in capacity building across all fields (i.e., manufacturing, supply chain and health systems strengthening). The company is engaging in non-exclusive voluntary licensing to enable generic supply of a non-communicable disease product in LMICs, the first agreement of its kind.

## CHANGES SINCE THE 2021 INDEX

- Established an ESG Council which co-creates and oversees the development of the ESG strategy, formulates ESG targets and raises relevant topics to the Trust & Reputation Committee.
- Created an Access Solutions Center of Excellence within Novartis Corporate Affairs and Global Health to provide guidance on the Access Principles implementation across the full organisation (Pharma, Oncology, Global Health, R&D).
- New ESG framework will prioritise access as one of the two most important materiality topics.
- Publicly disclosed disaggregated R&D expenses on priority diseases (excluding COVID-19) and separately for malaria.
- Joined the Neglected Tropical Disease Supply Chain Forum in 2021 with its Leprosy Donation programme to the World Health Organisation.
- Entered a partnership with Save the Children to launch a pilot community health project tackling child mortality in Kenya's Kibera and Mathare slums.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.
- As part of ATOM Coalition, agreed to a non-exclusive voluntary license (NEVL) with the Medicines Patent Pool (MPP) for nilotinib, indicated for leukaemia, becoming the first company to have signed a NEVL for an oncology medicine.
- Issued a EUR 1.85 billion sustainability-linked bond (SLB), reinforcing its commitment to ESG principles and the 2025 Patient Access Targets. The first of its kind in the healthcare industry and the first SLB incorporating social targets.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in 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. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

### SALES AND OPERATIONS

**Business segments:** Sandoz (generics and biosimilars) and Innovative Medicines.  
**Therapeutic areas:** Oncology, cardiovascular, renal and metabolism, Respiratory and allergy, Immunology, hepatology and dermatology, Neuroscience, Infectious diseases, Ophthalmology.  
**Product categories:** Innovative medicines, generic medicines, biosimilars.  
**M&A news:** Novartis acquired Vedere Bio in October 2020, Cadent in December 2020,

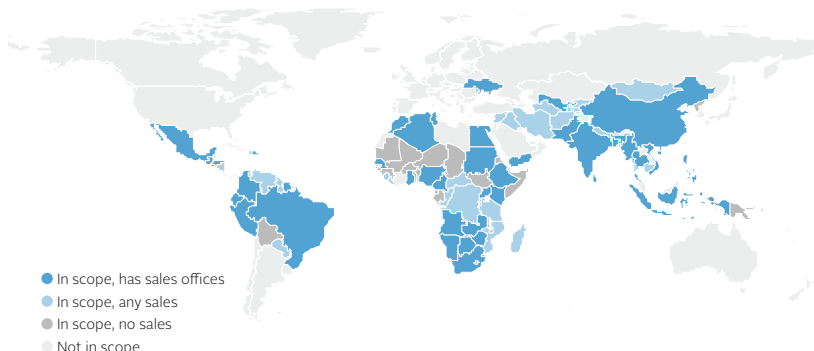
Arctos Medical in September 2021, GSK's cephalosporin antibiotics business in October 2021, Gyroscope Therapeutics in December 2021 and Kedalion Therapeutics in June 2022.

**Novartis' products are sold in 72 out of 108 countries in scope of the Index.** Novartis has sales offices in 43 countries, and sells via suppliers and/or pooled procurement in an additional 29 countries.

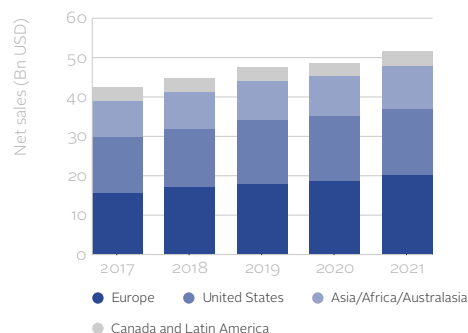
#### Net sales by segment (2021) – in USD

Innovative Medicines	42.00 bn
Sandoz	9.63 bn
<b>Total</b>	<b>51.63 bn</b>

#### Sales in countries in scope



#### Sales by geographic region



### SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

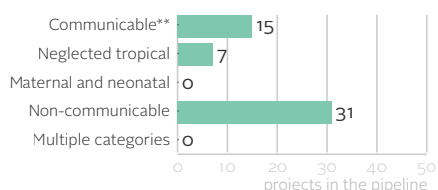
#### PIPELINE for diseases in scope

Novartis has a total of 53 R&D projects in scope with 22 of these projects targeting a priority disease. The other 31 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (11 projects) and Chagas disease (5). Of the projects targeting other diseases in scope, the focus is on oncology (22). Seventeen R&D projects are in late-stage development that target either a priority disease (6) or address a specific need in LMICs (11).<sup>\*</sup> Evidence of access planning was in place for 100% of these projects.

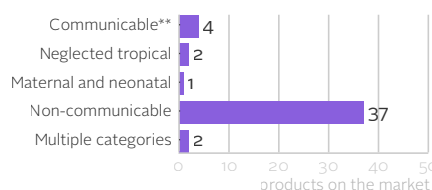
#### PORTFOLIO as selected for analysis by the Index

Novartis has 46 medicines in scope, 25 of which are on patent. 48% of these medicines (22) are on the WHO EML. The off-patent medicines target non-communicable diseases (NCDs) (14) such as cardiovascular diseases (6) mental health conditions (2) and cancer (3); neglected tropical diseases such as leprosy (2), communicable diseases such as tuberculosis (3); and one product for maternal haemorrhage. The on-patent medicines mainly target NCDs (25) such as cancer (10), respiratory diseases (6), cardiovascular diseases (3) and diabetes (2). In addition, one targets hepatitis B.

#### 53 projects in the pipeline



#### 46 products as selected for analysis by the Index<sup>†</sup>



#### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other <sup>***</sup>	Total
Targets established R&D priorities	10	2	4	4	1	0	1	22
Addresses needs of LMICs <sup>*</sup>			8	5	6	0	0	19
Other projects in scope			9	3	0	0	0	12

#### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	3	22			25
off patent	19	2			21
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other <sup>†</sup>				0	0

<sup>\*</sup>50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.  
<sup>\*\*</sup>Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.  
<sup>\*\*\*</sup>Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).  
<sup>†</sup>Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.  
<sup>‡</sup>Other includes vector control products.

# Novartis AG

## GOVERNANCE OF ACCESS

RANK 15

SCORE 3.43

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

**Evidence of access-related incentives at the executive level.** Novartis performs strongly. Novartis incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO and Executive Committee have 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 of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Novartis in Society Integrated Report.

**Performs above average in responsible promotional practices.** Novartis' sales agents are not solely incentivised on sales volume targets. However, the company sets sales incentives at the individual level for agents. Novartis does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g., payments for attending events or promotional activities), unless required by law or by local regulations, but it does have policies and procedures in place limiting transfers of values to healthcare professionals.

**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 evidence of 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.

**Does not publicly take a position of support on the Doha Declaration on TRIPS and Public Health.** Novartis does not publicly take a position of support of the Doha Declaration on TRIPS and Public Health as a whole, but it does publicly support, and/or adopts policies that it states exceed, several of the individual flexibilities embodied by the Doha Declaration. Novartis also supports the use of compulsory licensing in exceptional circumstances to address situations that require an extraordinary or urgent response to a pressing public need. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Novartis, like all other member companies in scope of the Index, is by default connected to this activity.

## RESEARCH & DEVELOPMENT

RANK 3

SCORE 3.70

**Access planning processes encompass all projects in the 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 (both in-house and collaborative) for diseases in scope of the Index. In general, Novartis begins developing access plans for R&D projects in Phase II of clinical development.

**An average-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (6/6) of late-stage projects.** Novartis has 22 projects, including six late-stage candidates in its pipeline, that target a priority product gap. These projects mainly focus on malaria. Novartis' six late-stage candidates targeting a priority product gap have access plans in place. The plans consider the availability and affordability of projects in development. For two projects targeting malaria, Novartis plans to expedite access by registering via the Marketing Authorization for Global Health Products (MAGHP) procedure in Switzerland. This aims to improve and accelerate

access to products in LMICs by involving national regulatory authorities in sub-Saharan Africa who will participate actively in the assessment in order to reduce approval timelines.

**Many projects address a public health need in LMICs,\* with 100% (11/11) of late-stage projects covered by access plans.** In this analysis, Novartis 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 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 of the Index and/or are first-in-class molecules or first-in-formulation projects. Projects target several diseases in scope of the Index including cancer, chronic obstructive pulmonary disease and sickle cell disease. Novartis provides evidence of access plans for all 11 late-stage projects which mainly focus on equitable pricing strategies and registration preparation in countries relevant to the Index.

**Publicly discloses disaggregated R&D investment data for priority diseases, neglected tropical diseases and stages of development.** In addition, Novartis also discloses fully disaggregated R&D investment data to Policy Cures Research.

**Four of the five R&D capacity building initiatives included meet all Good Practice Standards.** Novartis' performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, for the Ghana Sickle Cell Disease (SCD) Scientist Training Program, Novartis partners with the Sickle Cell Foundation of Ghana to train scientists that are working in the field of SCD. Training includes remote mentoring of scientists and a Postdoctoral Fellowship in natural product drug discovery at Novartis research labs.

\*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, 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.

## PRODUCT DELIVERY

RANK 4

SCORE 4.08

**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, LICs and a subset of LMICs.

**Publicly discloses information on patent status.** Like most of its peers, Novartis discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Novartis discloses patent information, including filing date, grant number, grant date and jurisdiction.

**Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers.** Novartis engaged in three new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

**Uses licensing agreements to enable generic supply.** After the period of analysis, Novartis signed a non-exclusive licensing agreement with the Medicines Patent Pool (MPP) for its oncology medicine, nilotinib (Tasigna®), the first agreement of its kind for a non-communicable disease product.

**Filed to register new products in 15 countries in scope on average.** Novartis has filed one out of ten of its most recently registered products in half of the relevant top 10 high burden countries. Among new products, Erenumab (Aimovig®), indicated for migraine, has been filed for registration in five high burden countries in scope of the Index (Brazil, Egypt, Indonesia, Thailand and Vietnam). Among old products, its most widely registered is sacubitril/valsartan (Entresto™), indicated for ischaemic heart disease, filed for registration in 48 countries relevant to the Index, including five high burden disease countries (Armenia, Egypt, Republic of Moldova, Ukraine and Uzbekistan).

**Has access strategies for all supranationally procured products in scope of this analysis.** Novartis has an average performance in securing access for products procured supranationally. For two of the four products assessed in this category, it demonstrated strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, the company offers the same price in South Africa for the malaria medicine artemether/lumefantrine (Riamet®/Coartem®) as it does in the Global Fund eligible countries. Novartis provides evidence of patient reach, reporting that approximately 26,000 patients in South Africa have received the product through the public channel in the period from April 2020 to February 2022.

**Has access strategies for its healthcare practitioner-administered products in scope of this**

**analysis.** Novartis has an average performance in this area. For two of the four products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). Novartis makes efforts to reach additional patients using pricing strategies considering relevant payers' ability to pay. For example, the company launched an Emerging Market Brand of crizanlizumab (Adakveo®), a treatment for sickle cell disease in India. Known as Ryverna, the product is currently available at a lower price than the original brand in several Indian national accounts, in accordance with the Novartis Global Oncology Pricing Tiers Guidance, and the company is working for inclusion in further state tenders. In addition, Novartis implemented a patient support programme to supply the medicine at no cost to eligible patients. Novartis provides evidence of how patient reach has been increased through these approaches.

**Has access strategies for the majority of self-administered products in scope of this analysis.** Novartis leads in this area. For four of the five products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC), including efforts to reach additional patients applying pricing strategies considering relevant payers' ability to pay. For example, in India, Novartis supplies nilotinib (Tasigna®) and ribociclib (Kisqali®) through national tenders. In addition, the company provides access to nilotinib to patients in out-of-pocket segments via the Novartis Oncology Access program, a contributions model where the company bears the majority of the cost. The programme also includes disease counselling activities to improve compliance and adherence to the treatment. Novartis provides evidence of how patient reach has been increased through the approaches used.

**Four of the five manufacturing capacity building initiatives included meet all Good Practice Standards.** Novartis' performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, since 2019 Novartis has worked on the Hibiscus transfer project, supporting contract manufacturers to improve the quality of their production and reduce their carbon footprint.

**All five supply chain capacity building initiatives included for analysis meet all Good Practice Standards.** Novartis is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. Through the Value Chain Academy, Novartis offers educational workshops for quality in supply, falsified medicines and supply chain management. These courses are offered to several supply chain stakeholders including governmental associations, distributors, hospital

pharmacies and non-governmental organisations.

**All five health systems strengthening initiatives included for analysis meet all Good Practice Standards.** Novartis is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, in the Strengthening the Translational Ecosystem for Lifesaving Local Access initiative, Novartis and academic partners have developed and are piloting a logistics management information system with the aim to reduce supply chain bottlenecks and improve access to medicines.

**Has engaged in scaling up four and piloting three inclusive business models.** Novartis leads in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Novartis Biome SSA is an innovation hub that was initiated in November 2021 and spearheads the development of innovative local sustainable business models and technology-driven solutions to improve access to healthcare in the sub-Saharan Africa region.

**Performs above average in terms of ensuring continuous supply of medicines in LMICs.** Novartis is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

**Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days.** Novartis has a policy for reporting SF medicines to both national health authorities and the WHO within seven days. The policy classifies incidents following categories according to the impact or potential impact and degree of severity, which may enable faster action.

**Donates in response to expressed need and monitors delivery.** Novartis has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it shows evidence of monitoring the delivery of donations to recipient organisations.

**Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria.** In one programme, Novartis publicly commits itself to contributing to the elimination of leprosy by donating the combination of clofazimine (Lamprene®), dapsone (Dapsone) and rifampicin (Rimactane®) from 2000 to 2025 in 83 countries in scope of the Index.