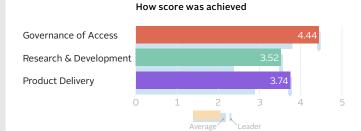
RANK	SCORE
1	3.78
4 (2022)	

Stock exchange: SWX • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 78,407

## PERFORMANCE IN THE 2024 INDEX

1<sup>st</sup> place. Novartis is a leading company and is a top performer in the Governance of Access and Research & Development Technical Areas. It also performs strongly in Product Delivery and demonstrates Best Practices in both Research & Development and Product Delivery.



## **OPPORTUNITIES FOR NOVARTIS**

Improve the quality and broaden the geographic reach of access plans. Novartis has access plans for almost all of its late-stage projects. The company can expand its plans, for example, by including equitable pricing and/or licensing and broadening the geographic coverage of these plans to focus on more low- and lower-middle-income countries. For example, the access plan for EYU688, a project currently in Phase II for dengue, can be expanded to include more than three countries in scope.

Expand technology transfer initiatives for its products to additional countries. Novartis launched three technology transfer initiatives in 2023 and 2024 for its diabetes, epilepsy and cardiovascular disease treatments vildagliptin (Galvus®), vildagliptin/metformin (GalvusMet®), carbamazepine (Tegretol®) and amlodipine/valsartan (Exforge®). The company can engage in additional technology transfer efforts for cardiovascular disease products in more countries, including those in sub-Saharan Africa. **Expand access to innovative products.** Novartis has demonstrated implementing access strategies across different income country classifications. It can continue to expand access by implementing equitable access strategies particularly in low-income countries. For example, for its innovative products ribociclib (Kisqali®), indicated for breast cancer, and inclisiran (Leqvio®), indicated for cardiovascular diseases.

Publicly report on the progress and outcomes of the Sub-Saharan Africa Business Unit. Novartis launched its inclusive business model in 2019, aiming to broaden patient reach and availability of its medicine portfolio, including 12 products in scope across 44 countries in scope. However, there is limited public information on where the products included in the model are available and how many patients the model has reached. The company can continue expanding access in these countries and report on where its products are supplied and the number of patients reached.

### **CHANGES SINCE THE 2022 INDEX**

- Completed a 100% spin-off of its generics and biosimilars division, Sandoz, in October 2023 and merged its Pharmaceutical and Oncology business units into an Innovative Medicines unit.
- Refined its framework for equitable access to ensure continued commitment and guidance to global and local teams following the Sandoz spin-off.
- Established regular assessments of climate scenarios and the potential rise of climatesensitive diseases (e.g., malaria, dengue, cardiovascular conditions), to inform its portfolio strategy.
- Collaborated with strategic diagnostic partners, such as PerkinElmer (Revvity), to address unmet needs of Sickle Cell Disease in sub-Saharan Africa.

- Progressed into Phase II clinical trial for an oral drug against visceral leishmaniasis in Ethiopia, together with the Drugs for Neglected Diseases initiative (DNDi).
- Announced move to Phase III study for novel ganaplacide/ lumefantrine-SDF combination in adults and children with malaria, together with Medicines for Malaria Venture.
- Signed a perpetual license agreement with Cipla to grant permission to manufacture and market its diabetes drug vildagliptin (Galvus<sup>®</sup>) and its combination brands from 1 January 2026.
- Partnered with Vision Catalyst Fund and Clinton Health Access Initiative (CHAI), Cambodia in 2023 to increase access to treatment for people living with diabetes, hypertension and eye diseases in Cambodia.
- Partnered with the General Authority for Health Insurance Mongolia, the Oddariya Foundation and Health for All to address service delivery and disease management for hypertension, diabetes and dyslipidemia at primary and secondary care levels.
- Updated its position on intellectual property (IP), which now declares support for the Doha declaration on TRIPS and Public Health.
- In August 2024, after the period of analysis, Novartis entered into an IP sharing agreement with The Kids Research Institute Australia, an Australian research institute, to accelerate development of patient-centric formulations to treat bacterial diseases in underprivileged paediatric populations.

### SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, immunology, neuroscience, oncology, renal & metabolic Product categories: Innovative medicines M&A news: Novartis acquired Kedalion Therapeutics for an undisclosed amount in 2022. In 2023, it acquired DTx Pharma for USD 500mn and

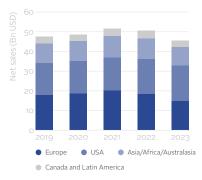
### Sales in countries in scope

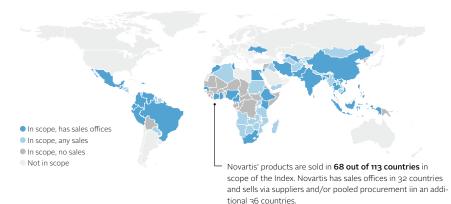
Chinook Therapeutics for USD 3.5bn, and divested its CGT CDMO CELLforCure to Seqens for an undisclosed amount. In 2024 it acquired Calypso Biotech for USD 425mn; SanReno Therapeutics for an undisclosed amount; IFM Due for USD 835mn; and MorphoSys AG for USD 2.89bn.

### Net sales by segment (2023) – in USD

Promoted brands	31.82 bn
Established brands	13.62 bn
Total	45.44 bn

### Sales by geographic region\*





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

#### **PIPELINE** for diseases in scope

Novartis has 61 R&D projects in scope, 27 of which target priority diseases, focusing on malaria (10), Chagas disease (5) and dengue (5). The remaining 34 projects target other diseases in scope, including cancer (15), cardiovascular diseases (9) and kidney diseases (4). Of the 61 R&D projects, 25 are in late-stage development, with evidence of access planning for 96% (24/25) of these.

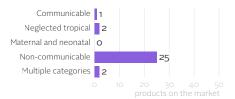
16

34

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

Novartis has 30 medicines in scope, 11 of which are listed on the WHO EML and 21 are on patent. Its medicines target mostly non-communicable diseases (25), including cancer (11), asthma and COPD (6) and cardiovascular diseases (4). It has 1 medicine for the communicable disease, malaria (1), and some medicines for neglected tropical diseases, such as leprosy (1), food-borne trematodiases (1), and 1 for both leprosy and TB (1). In addition, Novartis has 1 medicine indicated for both pregnancy hypertensive disorders and cardiovascular diseases.

### 30 products in the portfolio



# Breakdown of projects

61 projects in the pipeline

Communicable

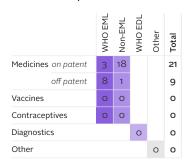
Neglected tropical

Maternal and neonatal o

Non-communicable

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	11	4	3	6	1	1	1	0	27
with access plan				6	1	1	1		9
Other projects in scope			18	7	9	0	0	0	34
with access plan				6	9	0	0		15

### Breakdown of products



\*Sales between 2019 and 2022 include Novartis' generic portfolio, Sandoz.

### **GOVERNANCE OF ACCESS**

#### 1 SCORE 4.4

1<sup>st</sup> place. Novartis leads in this Technical Area, showing a significant improvement since the last Index. It updated its intellectual property statement to express support for the Doha Declaration on TRIPS and Public Health. Further, the company provides evidence of a patient reach process that covers all products and countries in scope of the Index, as well as public reporting of the underlying methodology and resulting patient reach numbers.

The highest responsibility for access lies directly with the Board, namely with the Governance, Sustainability and Nomination Committee. Novartis incentivises its senior executives and in-country managers to act on access to medicine with financial and nonfinancial rewards. The CEO and Executive Committee have long-term access-related incentives included in their performance targets.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy.

Its strategy, embedded in its Novartis Access Principles, covers all therapeutic areas in which the company is involved. Novartis publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available and updated regularly in its Integrated Report. Shows comparatively strong commitment to responsible business practices. Novartis sets individual-level targets for sales agents, but incentives are not solely based on sales volume. It also assesses whether performance is aligned with the company's Code of Ethics and Values & Behaviors. Novartis has a public policy on ensuring ethical interactions with healthcare professionals. Further, it declares that transfers of value for healthcare professionals (e.g., payments for consulting) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novartis performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Novartis also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

### Novartis publicly supports the Doha Declaration on TRIPS and Public Health. The

company emphasises the balances and flexibilities embedded in the agreement and states that compulsory licensing should be used in limited, exceptional circumstances for which it was designed.

Fulfils most criteria across 4 processes for measuring and reporting patient reach. For its innovative medicines sustainability-linked bond process, which covers some of its products and all countries (where the company operates) in scope of the Index, Novartis publicly provides the underlying equation, metrics and assumptions. The resulting patient reach numbers are published regularly and demonstrate improvements. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

#### **RESEARCH & DEVELOPMENT**

#### RANK 1 SCORE 3.52

1<sup>st</sup> place. Novartis leads in this Technical Area. It has a mixed pipeline including non-communicable diseases and priority diseases, with access plans in place for almost all its late-stage pipeline candidates. It demonstrates Best Practice for its malaria access plans and, on average, has access plans with greater depth and breadth compared to peers. It performs strongly in its R&D capacity building activities, and publicly discloses disaggregated R&D investment data by phase of development and for priority neglected diseases.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public commitment addressing its systematic approach to access planning for LMICs.

Large-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (9/9) of the late-stage candidates. Priority R&D pipeline of 27 projects, including 9 late-stage projects that target a priority gap. The company focuses on various priority areas, including malaria, Chagas disease and dengue. All of Novartis's 9 late-stage candidates targeting a priority product gap have evidence of an access plan in place, mostly focusing on registration preparation, equitable pricing and WHO prequalification.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 94% (15/16) of late-stage projects covered by access plans. The company has 16 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, cardiovascular diseases and kidney diseases. Novartis provides evidence of access plans for 15 of its 16 late-stage projects, mostly focusing on post-trial access, registration preparation and the inclusion of special populations in clinical trials.

Novartis publicly discloses disaggregated R&D investment data for malaria and phase of development (Phase I/II vs Phase II/III). It also discloses anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is Speaking Books, an initiative that aims to increase patients' willingness to participate in clinical trials by improving their understanding of trials.

### PRODUCT DELIVERY

### RANK 2 SCORE 3.74

**2<sup>nd</sup> place.** Novartis performs strongly in this Technical Area. It demonstrates Best Practice by registering innovative products widely in LMICs and operating an inclusive business model to improve access to its products in multiple low-income and least developed countries. It implements access strategies for which it demonstrates Best Practice in reporting outcomes. It has also launched plans for some products to increase low-income countries coverage. Novartis engaged in a new non-exclusive voluntary licensing agreement for one compound during the period of analysis.

## Novartis registers newer products\* in 23 countries in scope on average. It registers 80% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's sacubitril/valsartan (Entresto<sup>™</sup>), indicated for heart failure, is most widely

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registered, totalling 50 countries. The company reports engaging in various mechanisms to facilitate the registration of multiple products.

Supplies 2 products in scope through supranational agreements. Novartis supplies its malaria treatment, artemether/lumefantrine (Riamet®/ Coartem<sup>®</sup>), via The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and clofazimine (Lamprene®) for MDR-TB via the Global Drug Facility. For both products, the company demonstrates access strategies for at least 1 country not eligible for such supply. For example, the company offers the same price in South Africa for clofazimine as it does in Global Fund-eligible countries. Novartis provides patient reach data for all its strategies. For example, in Angola, a non-eligible country, 3,204,555 patients have received artemether/lumefantrine in the public sector in the period from May 2022 to February 2024.

Access strategies for its healthcare practitioner (HCP)-administered products in some countries, supported by information on outcomes. For the 2 products selected for analysis, Novartis provides access strategy examples in UMICs and LMICs that show some efforts in improving affordability and availability. For example, in Brazil (UMIC), the company launched a second brand of its product inclisiran (Leqvio®), indicated for atherosclerotic cardiovascular disease (ASCVD), and plans to launch the second brand also in an LIC. Pricing strategies are complemented by additional strategies and health system strengthening initiatives. For inclisiran, the company has a comprehensive approach in Egypt (LMIC), including microfinancing solutions, to support out-of-pocket expenses, capacity building and public-private partnerships to strengthen healthcare systems and improve ASCVD patient reach. Whereas for its asthma product, omalizumab (Xolair®), the company launched patient support programmes in Egypt to cover the costs of IgE testing and administration. The company has goals to increase access and advance its strategies. Novartis shares patient reach data, with evidence of increasing reach, supported by information on the approaches used to track the strategies' outcomes.

# Access strategies for most self-administered products, supported by information on out-

**comes.** For 3 of the 5 products selected for analysis, Novartis has implemented access strategies in all 3 country income classifications (UMIC, LMIC, LIC). The remaining 2 products have access strategies in UMICs and LMICs, with launches planned in LICs. In all the strategies analysed, the company demonstrates efforts to consider different payers' ability to pay, aiming to improve the affordability of its products. For example, in India (LMIC) and South Africa (UMIC), a second brand of erenumab-aooe (Aimovig®), indicated for migraine, was launched with a reduced price compared to the original global brand; it will also launch in an LIC in Africa soon. In addition, a second brand for ribociclib (Kisqali<sup>®</sup>), indicated for breast cancer, has been supplied in India, with plans for launch in several LICs. Most pricing strategies analysed are complemented by additional strategies, such as patient support programmes, that target out-of-pocket payments or other barriers to treatment, such as screening, patient follow-up and adherence. For most of the products assessed, the company has goals to increase access to its products and patient reach. It provides evidence of increasing patients reached via its strategies, supported by some information on the approaches applied to measure outcomes.

Novartis publicly commits not to file for or enforce patents for all products in the majority of countries in scope. This applies to all least developed countries and LICs, over half of UMICs and most LMICs. However, the list of countries to which this commitment applies is not publicly available.

## Publicly discloses product patent status for

countries in scope. Novartis publicly discloses patent information for all small molecules via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Novartis has 1 non-exclusive voluntary licensing agreement to enable generic supply of nilotinib, indicated for chronic myeloid leukaemia. The licence was issued in October 2022, shortly before the expiration of the primary patent, and covers 43 countries in scope. It is the first non-exclusive voluntary licence for a non-communicable disease. The terms of the licence are publicly available.

None of the 3 manufacturing capacity building initiatives included for analysis meet all GPS. Despite not meeting all GPS, in 1 initiative, Novartis is transferring technology to Moroccan manufacturer Sothema to fully produce diabetes treatment vildagliptin (Galvus® 50mg) and conduct primary and secondary packaging for epilepsy treatment (Tegretol® CR 200mg & 400mg). Novartis will support Sothema to improve the level of Good Manufacturing Practice compliance to supply to the local market.

Three of the four supply chain capacity building initiatives included for analysis meet all GPS. For example, Novartis developed Authentifield, a testing device that aims to reduce the time needed to detect and report falsified medicines. The devices have been deployed to 70 countries, 24 of which are in scope. Novartis is exploring the feasibility of empowering external stakeholders with the solution in the long term.

### All 5 health system strengthening initiatives included for analysis meet all GPS. In 1 initiative, Novartis aims to reduce cardiovascular risks

in urban environments by supporting local stakeholders to roll out a set of health interventions. The interventions are tailored to the local context and can include, for example, clinical decision support tools and data collection. This CARDIO4Cities approach is actively scaling in Brazil to more municipalities, is transitioning to government ownership in Senegal, and has transitioned to government ownership in Mongolia. It is now being scaled to additional countries, such as Rwanda.

Novartis remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development. In 1 agreement, in collaboration with the Wellcome Trust, Novartis has shared IP assets aiming to discover treatments for Chagas disease. However, the company has not engaged in new agreements during the period of analysis.

Fulfils all criteria for ad hoc donations. Novartis has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Novartis publicly commits to continuing longterm donation programmes to support the elimination of leprosy and control the outbreak of food-borne trematodiases. One of its programmes is active in approximately 80 countries in scope, with the company pledging to donate the combination of clofazimine (Lamprene®), dapsone (Dapsone®) and rifampicin (Rimactane®) through 2025 to help eliminate leprosy.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Novartis is transferring technology to Indian manufacturer Medreich for primary and secondary packaging of the diabetes treatment vildagliptin/metformin chlorydrate (GalvusMet FCT).

Novartis has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to both national or local regulatory authorities and the WHO within 7 days. The policy classifies incidents into categories according to the impact or potential impact and degree of severity, which may enable faster action.

Novartis operates an inclusive business model that covers 19\*\* products in 46\*\*\* countries, including 30 low-income and least developed countries. Launched in 2019, the sub-Saharan Africa Unit currently offers medicines for indications, such as cardiovascular disease, sickle cell, neurology, malaria and diabetes<sup>†</sup>. The model addresses affordability (e.g., through second brands, social business), healthcare professional training, and health system strengthening through partnerships.

<sup>+</sup>On 4 October 2023, Novartis completed its spin-off of Sandoz, transferring its generic portfolio to the newly independent company.