

# Novartis AG

This table is part of a [November 2023 report](#) that looks at what actions each company in scope of the Antimicrobial Resistance (AMR) Benchmark has taken with regards to each of the Opportunities set out in its 2021 AMR Benchmark Report Card. The full 2021 Report Card is also included in this PDF.

Since the publication of the 2021 AMR Benchmark, Novartis has completed a 100% spin-off of its generics and biosimilars business, Sandoz. On 4 October 2023, Sandoz became an independently listed company. This report provides updates on opportunities identified in Novartis's 2021 Benchmark Report Card, looking at progress over the two-year period and incorporating information about both Sandoz and Novartis.

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
<p><b>Engage in antibacterial and antifungal R&amp;D including medicines and vaccines against priority pathogens.</b> Novartis contributes to the AMR Action Fund, a joint venture that aims to bring 2-4 new antibiotics to the market by 2030 and has a partnership with GARDP to provide antibiotic formulations accessible for children with drug-resistant infections. Novartis can engage in in-house R&amp;D, through acquisition or collaboration with other companies, or by joining existing public private partnerships, to target resistant pathogens for which R&amp;D is limited, such as <i>Campylobacter spp.</i> and <i>H. pylori</i>.</p>	<p>Novartis did not report any progress on this Opportunity, referring to its earlier contributions to the AMR Action Fund.</p>
<p><b>Ensure compliance to antibacterial discharge limits at suppliers sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites.</b> Novartis can expand its requirements to quantify discharge levels as it does for its own sites to all its suppliers' sites and track compliance with set limits. It can publicly disclose the results including the discharge levels. The company currently publishes information on compliance at own sites with pharmaceutical limits that include, but is not specific to, antibacterials. Novartis can also apply limits directly in effluent to fully mitigate AMR risk.</p>	<p>Novartis continues to report implementing the AMR Industry Alliance guidelines. The company publicly reports that, in 2022, it engaged with over 100 priority suppliers to assess their discharge levels against the standards of the AMR Industry Alliance. However, Novartis does not report any developments on the number of its own and supplier sites that are compliant with discharge limits.</p> <p>Similar to 2021, Novartis does not publicly disclose audit results containing antibacterial discharge levels for both its own sites and suppliers' sites. Furthermore, the company does not disclose the names and locations of its suppliers.</p>
<p><b>Expand registration and ensure availability of antibacterial and antifungal medicines.</b> Novartis can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as daptomycin and tigecycline, to more countries, including low-income countries, with a high burden of disease.</p>	<p>Novartis did not report any progress related to expanding the registration of its antibiotics and antifungals to additional countries in scope of the Benchmark. In 2022, Sandoz announced plans to invest EUR 50M to increase manufacturing capacity for finished dosage form penicillins at its manufacturing site in Kundl, Austria. This brings the total investment in Sandoz's antibiotics manufacturing network in Europe to over EUR 250M. However, the extent to which this expansion will increase availability of penicillins in countries in scope is unclear.</p>

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
<p><b>Fully decouple incentives for sales agents from sales volumes.</b> In Novartis' limited promotional activities directed at health-care professionals, it links part of its sales agents' incentives to sales volumes of antibacterial and antifungal medicines. It can fully decouple such incentives for sales agents.</p>	<p>Novartis did not report any progress on this Opportunity.</p>
<p><b>Publicly share raw data from surveillance programme.</b> Novartis supports the national Diagnostics of Central Nervous System Bacterial Infections (KOROUN) programme, which is managed by the Polish National Medicines Institute. Either Novartis or the managing partner can publicly share raw data from this surveillance programme.</p>	<p>Sandoz continues to support the KOROUN surveillance programme. However, Novartis did not report updates in regard to publicly sharing the raw data from this programme.</p> <p>In 2022, Sandoz announced an AMR surveillance programme in collaboration with Ares, a subsidiary of OpGen Inc.,. However, Novartis did not report any updates in regard to publicly sharing the raw data from this programme.</p>

**Overall Performance**

2020 2021

54% 63%▲

# Novartis AG

Large R&D-based pharmaceutical company

Stock exchange: SWX • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 105,794

## PERFORMANCE

Novartis performs above average overall in its evaluated Research Areas compared to the other large research-based pharmaceutical companies in scope.

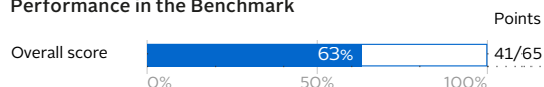
**R&D:** Novartis no longer carries out R&D projects that target pathogens in scope of the AMR Benchmark.

**Responsible Manufacturing:** Performs strongly. Reports comprehensive environmental risk-management strategy for own sites and suppliers; co-leads in reporting compliance with limits at own sites, audits external private and public waste-treatment plants.

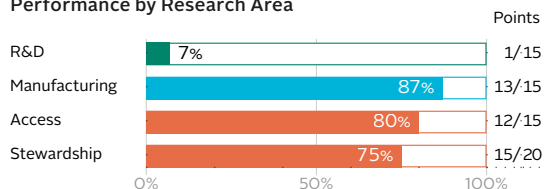
**Appropriate Access:** Performs strongly. Files some of its relevant products (on- and off-patent products) for registration in access countries. Reports several strategies to expand access and ensure continuous supply of its relevant products.

**Stewardship:** Performs well. It decouples sales incentives for a significant portion of its sales by using tenders. It supports a surveillance programme in Poland of which aggregated results are publicly shared. It reports comprehensive conflict of interest mitigation for its educational programmes. It adapts brochures for patients.

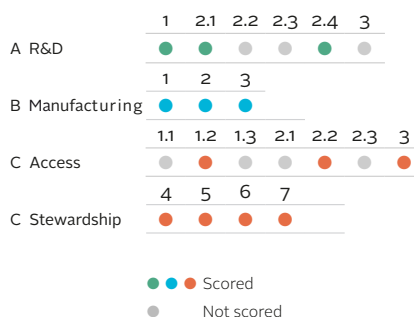
### Performance in the Benchmark



### Performance by Research Area



### How Novartis was evaluated



## OPPORTUNITIES FOR NOVARTIS

**Engage in antibacterial and antifungal R&D including medicines and vaccines against priority pathogens.** Novartis contributes to the AMR Action Fund, a joint venture that aims to bring 2-4 new antibiotics to the market by 2030 and has a partnership with GARDP to provide antibiotic formulations accessible for children with drug-resistant infections. Novartis can engage in in-house R&D, through acquisition or collaboration with other companies, or by joining existing public private partnerships, to target resistant pathogens for which R&D is limited, such as *Campylobacter* spp. and *H. pylori*.

**Ensure compliance to antibacterial discharge limits at suppliers sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites.** Novartis can expand its requirements to quantify discharge levels as it does for its own sites to all its suppliers' sites and track compliance with set limits. It can publicly disclose the results including the discharge levels. The company currently publishes information on compliance at own sites with pharmaceutical limits that include, but is not specific to, antibacterials. Novartis can also apply limits directly in effluent to fully mitigate AMR risk.

**Expand registration and ensure availability of antibacterial and antifungal medicines.** Novartis can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as daptomycin and tigecycline, to more countries, including low-income countries, with a high burden of disease.

**Fully decouple incentives for sales agents from sales volumes.** In Novartis' limited promotional activities directed at healthcare professionals, it links part of its sales agents' incentives to sales volumes of antibacterial and antifungal medicines. It can fully decouple such incentives for sales agents.

**Publicly share raw data from surveillance programme.** Novartis supports the national Diagnostics of Central Nervous System Bacterial Infections (KOROUN) programme, which is managed by the Polish National Medicines Institute. Either Novartis or the managing partner can publicly share raw data from this surveillance programme.

## CHANGES SINCE 2020

- Approval secured of a OneNovartis AMR program to minimize spread of AMR by focusing efforts where the company can make a difference. The program prioritises appropriate access, responsible manufacturing and responsible use. The initiative was launched in May 2021.
- In July 2020, Sandoz and the Austrian government formed a public-private partnership to increase production capacity at Sandoz's antibiotics manufacturing site in Kundl, Austria. Sandoz commits to investing more than USD 175 mn over the next five years to new antibiotics manufacturing technology.
- Novartis has expanded registration of its sample off patent/generic medicines to more access countries, meeting the opportunity provided in the 2020 Benchmark.
- Since 2019, Novartis supports the Diagnostics of Central Nervous System Bacterial Infections (KOROUN) study, a national AMR surveillance programme focused on community-acquired respiratory tract infections in Poland. Before this programme Novartis was not involved in AMR surveillance.

**SALES AND OPERATIONS**

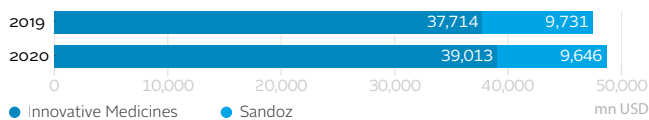
**Therapeutic areas:** Cardiovascular, renal and metabolism; Immunology, hepatology and dermatology; Neuroscience; Oncology; Ophthalmology; Respiratory.

**Business segments:** Innovative Medicines, Sandoz

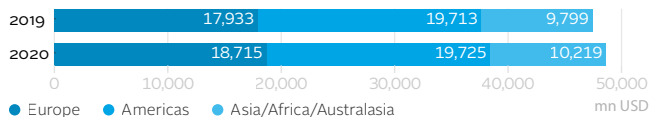
**Product categories:** Biosimilars, Generic medicines, Innovative medicines

**M&A since 2020:** In February 2021, Novartis division Sandoz signed an agreement to acquire GSK’s cephalosporin antibiotic business for USD 350 mn in addition to milestone payments up to USD 150 mn.

**Net sales by business segment**



**Net sales by region**



**PIPELINE for pathogens in scope**

Novartis is currently not developing any projects targeting the pathogens in scope\*.

**PORTFOLIO for pathogens in scope**

**Comparatively large portfolio:** At least 109 products: 96 antibacterial medicines; 13 antifungal medicines

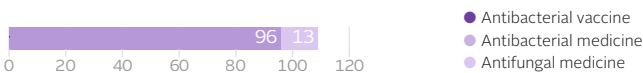
**Off-patent/generic medicines:** 10 of 109 were selected for analysis\* (amoxicillin [A], amoxicillin/clavulanic acid [A], clarithromycin [W], daptomycin [R], itraconazole [F], levofloxacin [W], linezolid [T], rifampicin [T], tigecycline [R], voriconazole [F])

**AWaRe medicines\*\*:** 21 Access group; 35 Watch group; 2 Reserve group  
**Anti-TB medicines\*\*:** 9

**Pipeline for priority pathogens**



**Products on the market**



**PERFORMANCE BY RESEARCH AREA**

**A RESEARCH & DEVELOPMENT** Evaluated: medicine & vaccine pipelines for priority\* bacteria & fungi

**A.1 Investments in R&D**

Novartis did not report investments during 2019 and 2020 in R&D for antibacterial and antifungal medicines and/or vaccines for pathogens in scope. Novartis has pledged an unknown amount to the AMR Action Fund over the next 10 years.

**A.2.2 Novelty of pipeline**

Novartis is not eligible for this indicator as it does not have any R&D candidates in clinical development.

**A.3 Access and stewardship planning**

Novartis is not eligible for this indicator as it has no projects targeting pathogens in scope in late-stage clinical development. Companies are expected to have plans in place for pipeline projects in Phase II and beyond.

**A.2.1 Novartis does not engage in R&D for products in scope**

The company does not report any project in its pipeline targeting pathogens in scope.

**A.2.3 Not active in vaccine development**

Novartis is not active in vaccine development targeting pathogens in scope.

**A.2.4 Critical and/or urgent priorities**

Novartis is not eligible for this indicator as it does not have any R&D candidates in development.

Pipeline targeting priority pathogens: 0 As at 24 September 2021



Novartis is currently not developing any projects targeting the pathogens in scope\*.

\* See Appendix V for information about eligibility for R&D projects and Appendix VII for eligibility criteria of products.

\*\* Listed on the 2019 WHO EML.

**B RESPONSIBLE MANUFACTURING** Evaluated: antibacterials manufacturing (APIs and drug products)**B.1 Comprehensive environmental risk-management for own sites and suppliers; audits external private and public waste-treatment plants**

Novartis reports a comprehensive strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits every 2-4 years. It reports setting discharge limits in the receiving environment for all antibacterials manufactured at its sites, based on PNECs to limit AMR, as recommended by the AMR Industry Alliance. Discharge levels are quantified at all sites using a mass balance approach or chemical analysis, as applicable. It reports that compliance of own sites with discharge limits is tracked. It also publicly reports that 80% of its own sites are compliant with discharge limits for pharmaceuticals which include, but are not specific to, antibacterials.

Novartis requires third-party suppliers of antibacterials to follow the same standards, including limits based on PNECs. It reports conducting on-site audits every three years. It requests and reviews the discharge levels of its

suppliers. It is undisclosed how many of the 160 supplier sites report to have quantified discharge levels.

Novartis expects external private waste-treatment plants to comply with its general environmental standards. It audits external private and public waste-treatment plants at least every three years, based on risk. It requests external private and public wastewater treatment plants to provide dilution and flow rate data to inform the mass balance approach and employs conservative measures when needed.

**B.2 Publicly discloses some information on environmental risk management and compliance with limits for pharmaceuticals including antibacterials**

Novartis publishes some components of its environmental risk-management strategy. It is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Novartis publishes its commitment to setting discharge limits, at own and suppliers' sites, for pharmaceuticals in the environment which include but go beyond antibac-

terials. It publicly discloses that 80% of its own sites are compliant to these general limits. The discharge levels themselves are not published. Novartis also does not publish: (1) the results of environmental audits, conducted at its own sites, the sites of suppliers and/or external private and public waste-treatment plants; or (2) a list of these suppliers and plants.

**B.3 System in place to maintain production quality for own and suppliers' sites; no requests for official corrective action**

Novartis reports that its own sites and suppliers have a system to maintain high-quality antibacterial production consistent with international GMP standards. This includes periodic risk-based audits and tracking of corrective and preventive actions. Novartis also requires its suppliers to audit their own suppliers. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Novartis' own sites or any subsidiaries that manufacture antibacterials.

**C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS**

Evaluated: access activities relating to antibacterial & antifungal medicines & vaccines in 102 access countries\*\*\*

Novartis is not eligible for indicators: C.1.1, C.1.3, C.2.1 and C.2.3. For more information, see Appendix VII.

**C.1.2 Filed to register off-patent/generic medicines in 30 access countries on average**

Novartis performs above average, filing nine of its 10 relevant off-patent/generic medicines for registration in 30 access countries on average. Its most widely filed relevant product is amoxicillin/clavulanic acid, filed in 70 access countries. Three of its relevant products are filed in less than ten access countries. Six of its relevant products are filed for registration in at least one LIC.

**C.2.2 Several strategies to expand access to off-patent/generic medicines**

Novartis performs above average, with access strategies reported for four of its ten relevant off-patent/generic medicines. It aims to expand access to its off-patent/generic medicines in access countries through equitable pricing, tenders and competitive prices. It provides evidence of patient reach and geographic reach for all its reported approaches. Novartis Access pricing policy ranges the prices from USD 1 per treatment per month or at tailored prices. Novartis Sub-Saharan African (SSA) Unit takes a high-volume, lower-price approach to increase the patient reach. Novartis has set public goals to increase the patient reach twofold by 2022 and fivefold by 2025 through its SSA unit. In 2020, Novartis, through its Sandoz division, committed

to sell some of its medicines, of which antibiotics used to treat patients with COVID-19-related symptoms, at zero-profit to governments in up to 79 eligible low-income and lower-middle-income countries.

**C.3 Several strategies to ensure continuous supply**

Novartis performs above average, with strategies reported in all four areas assessed. Novartis ensures accurate demand planning and data sharing by following a monthly rolling process from one to 36 months in advance and ensures weekly data sharing for anti-infectives. Novartis mitigates against shortage risks by keeping buffer stocks for key starting materials, drug substance and drug products. It ensures dual sourcing when possible. It has set daily, weekly, and monthly KPIs to monitor its supply chain performance. Novartis reports one technology transfer initiative in Pakistan, to locally produce its penicillin portfolio. To mitigate against substandard and falsified products, Novartis monitors online platforms, uses data analytics, spectrometry technologies, anticounterfeiting packaging features and mobile applications.

\*\*\* 102 low- and middle-income countries where better access to medicine is most needed.

**C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP**

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

**C.4 Comprehensive COI mitigation strategies in place for its educational programmes**

Novartis performs strongly in conflict of interest (COI) mitigation for the five AMR-related educational programmes for HCPs assessed by the Benchmark. To mitigate COI for one programme, it provides financial resources to an independent third party (MedShr) to develop the programme. The remaining four programmes have all three COI mitigation strategies looked for by the Benchmark: (1) content is developed independently from its marketing department; (2) a pledge not to provide financial or material incentives to participants; and (3) it does not use branded materials.

**C.5 Engages in sales and marketing practices to address appropriate use**

Novartis performs above average in sales practices. It reports that it sells a significant portion of its antibacterial and/or antifungal medicines through tenders and does not have sales incentives linked to the sales volume of these tenders. Outside of these tenders, promotion of antibacterial and/or antifungal medicines is limited and the focus of such promotional activities is not on these medicines.

Novartis engages in marketing practices that aim to address the appropriate use of its

antibacterial and/or antifungal medicines. Its marketing materials include emerging resistance trends and/or include treatment guidelines for healthcare professionals: for azithromycin, cefixime, amoxicillin/clavulanic acid and cefpodoxime by including antimicrobial stewardship guidelines for healthcare professionals and by combining the most recent information from WHO's AWaRe categorization with information on resistance closely aligned with national guidelines for its top ten global antibacterial medicines.

**C.6 Makes one type of brochure and/or packaging adaptation to facilitate appropriate use by patients**

Novartis adapts brochures to facilitate the appropriate use of amoxicillin/clavulanic acid by patients. Novartis is middle-performing in this measure, taking account of paediatric use. It has created paediatric guidance for amoxicillin/clavulanic acid that focuses on correct dosing for children.

**C.7 Active in one AMR surveillance programme; openly publishes aggregated results**

Novartis is active in the national Diagnostics of Central Nervous System Bacterial Infections

(KOROUN) programme, which is managed by the Polish National Medicines Institute with support from Novartis and has been running since 2019. It is focused on community-acquired respiratory tract infections in Poland. Only the aggregated results are shared through open-access journal articles and the KOROUN website.