| RANK | SCORE |
|---|---|
| 11 | 3.07 |
| 10 (2022) | |

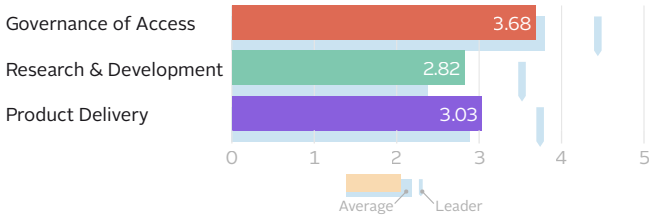
# Roche Holding AG

Stock exchange: SIX • Ticker: ROG.SW • HQ: Basel, Switzerland • Employees: 103,605

## PERFORMANCE IN THE 2024 INDEX

**11th place.** Roche is a middle-performing company. It performs above average in both Research & Development and Product Delivery, where it demonstrates Best Practice for registering its products widely and supplying its World Health Organization (WHO)-prequalified human papillomavirus (HPV) test to nearly 50 countries in scope of the Index. However, it performs below average in Governance of Access.

**How score was achieved**




## OPPORTUNITIES FOR ROCHE

**Ensure all late-stage R&D projects have comprehensive access plans.** Roche has access plans in place for one third of its late-stage projects. The company's access plans currently predominantly focus on plans for registration filings. To enhance the quality of these plans, the company can go beyond commitments to register in countries where clinical trials are conducted, incorporating additional access components, such as equitable pricing and licensing. For example, it can improve its access plans for giredestrant, in development for uterine and breast cancer, with clinical trials in Phase II and Phase III, respectively.

**Engage in technology transfer initiatives for additional oncology products.** Roche is engaged in technology transfer initiatives with manufacturers in China and Egypt for bevacizumab (Avastin®), a product indicated for multiple cancer types. The company can expand such initiatives to further products in its oncology portfolio, such as atezolizumab (Tecentriq®) and pertuzumab (Perjeta®).

**Expand access to its innovative products.** Roche has access strategies in place for its assessed products, but mostly focuses on upper-middle- and lower-middle-income countries and lacks access strategies in low-income countries. For example, it can expand access to two of its key products – trastuzumab/hyaluronidase (Herceptin®SC), indicated for breast cancer, and baloxavir marboxil (Xofluza®), indicated for influenza A and B – both of which are prioritised for licensing by public health organisations, through equitable access strategies and/or voluntary licensing to enable generic supply.

## CHANGES SINCE THE 2022 INDEX

- Received WHO prequalification for the Cobas® HPV Test, which is supplied at a standardised price to eligible LMICs as part of Roche's Global Access Program.
- Partnered with Jhpiego and the government of Ghana to enhance women's cancer care as part of the Ghana National Strategy for Cancer Control.
- Signed a memorandum of understanding with the Egyptian Drug Authority to shape the regulatory environment and undergo digital transformation.
- Signed a co-promotion agreement with Radiant Pharmaceuticals to provide medicines for severe diseases, including cancer, ophthalmology, and neurology in Bangladesh.
- Entered a five-year collaboration and licensing agreement with Moma Therapeutics to use its KnowledgeBase platform to identify novel cancer drug targets.
- Co-founded the Biospecimen Management Consortium to advance complex clinical research.
- Developing the first antibiotic to show progress against drug-resistant bacteria, Carbapenem-resistant *Acinetobacter baumannii* (CRAB).
- Donated medicines to earthquake-stricken Morocco in 2023 in response to requests from Morocco's Ministry of Health.
- Newly disclosed evidence of conducting fraud-specific risk assessments to mitigate risk of non-compliant and corrupt activities.
- Expanded the list of eligible countries in its Global Access Program from 82 to 89.

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## SALES AND OPERATIONS

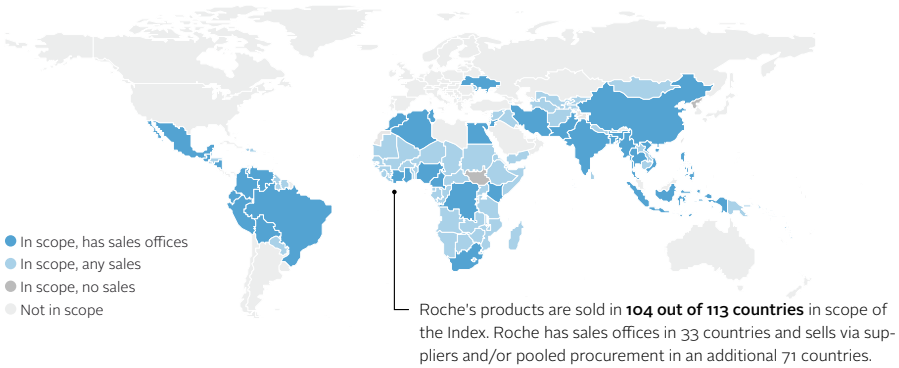
**Therapeutic areas:** Cardio-metabolic, diabetes, haematology, infectious diseases, inflammatory bowel diseases, neuroscience, oncology, ophthalmology, rare disease, respiratory, women's health
**Product categories:** Diagnostics, innovative medicines

**M&A news:** Roche acquired Good Therapeutics' PD-1 programme for USD 250mn, Televant Holdings for USD 7.1bn, and Carmot Therapeutics for USD 2.7bn in 2022, 2023 and 2024, respectively.

**Sales by segment (2023) – in CHF**

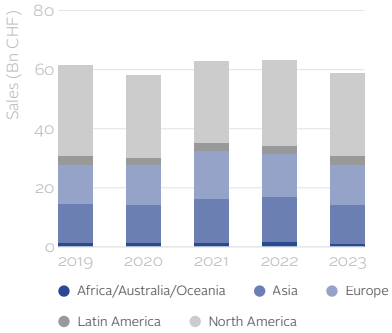
| | |
|---|---|
| Pharmaceuticals | 44.61 bn |
| Diagnostics | 14.1 bn |
| Total | 58.71 bn |

### Sales in countries in scope




Roche's products are sold in **104 out of 113 countries** in scope of the Index. Roche has sales offices in 33 countries and sells via suppliers and/or pooled procurement in an additional 71 countries.

### Sales by geographic region

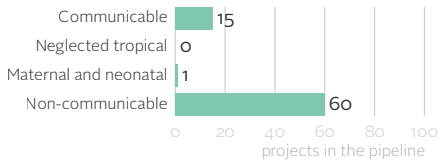



## SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

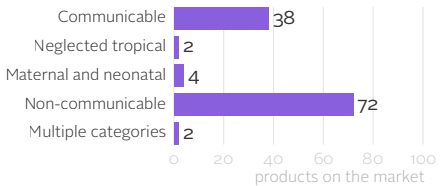
**PIPELINE** *for diseases in scope*
Roche has 76 R&D projects in scope, 13 of which target priority diseases, focusing on hepatitis B (3), coronaviral diseases (3) and other prioritised antibacterial-resistant infections (2). The remaining 63 projects target other diseases in scope, including cancer (46), Alzheimer's disease (6) and lower respiratory infections (3). Of the 76 R&D projects, 30 projects are in late-stage development, with evidence of access planning for 30% (9/30) of these. In addition, 4 diagnostics have been approved during the period of analysis.

**PORTFOLIO** *as selected for analysis by the Index*
Roche has 118 products in scope, including 25 medicines, 9 of which are listed on the WHO EML and 19 are on patent. In addition, the company has 81 diagnostics, all of which are on the WHO EDL, as well as 12 platform technologies. Roche's medicines mostly target non-communicable diseases (19), specifically cancer (16). Some of its medicines target communicable diseases (6), such as coronaviral diseases (2) and lower respiratory infections (2). Its platform technologies are for diseases such as respiratory infections (3), diabetes (3), cancer (2) and other diseases in scope. The diagnostics are for diseases such as cancer (35), hepatitis (B and C) (10), cardiovascular diseases (9) and HIV (8).

### 76 projects in the pipeline




### 118 products in the portfolio




### Breakdown of projects

| | Discovery | Pre-clinical | Phase I | Phase II | Phase III | Phase IV | Approval | Other | Total |
|---|---|---|---|---|---|---|---|---|---|
| Targets established R&D priorities | 0 | 0 | 1 | 3 | 0 | 0 | 4 | 5 | 13 |
| *with access plan* | | | | 2 | 0 | 0 | 1 | | 3 |
| Other projects in scope | | | 33 | 12 | 9 | 0 | 6 | 3 | 63 |
| *with access plan* | | | | 1 | 4 | 0 | 1 | | 6 |

### Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---|---|---|---|---|---|
| Medicines *on patent* | 3 | 16 | | | 19 |
| *off patent* | 6 | 0 | | | 6 |
| Vaccines | 0 | 0 | | | 0 |
| Contraceptives | 0 | 0 | | | 0 |
| Diagnostics | | | 81 | | 81 |
| Other | | | | 12 | 12 |

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## GOVERNANCE OF ACCESS RANK 13 SCORE 3.68

**13th place.** Roche performs below average in this Technical Area. The company incentivises its in-country managers to act on access to medicine; however, it does not disclose whether the CEO and senior executives are also incentivised towards access goals. Roche has a public policy that commits to ensuring ethical interactions with healthcare professionals in its code of conduct. However, it does not align with the standards set by the Index.

**The highest responsibility for access lies directly with the Board, namely with the Corporate Governance and Sustainability Committee.** Roche incentivises its in-country managers to act on access to medicine with financial and non-financial rewards. It does not disclose, however, whether the CEO/senior executives are also incentivised towards access goals.

**Comprehensive access-to-medicine strategy integrated within the overall corporate strategy.** Its strategy covers all therapeutic areas in which the company is involved. Roche publicly discloses its commitments to access to medicine, along with some company-specific measurable targets, goals and objectives. Reporting is mostly clear, linked to these goals, centrally available and updated regularly in its Annual Report.

**Shows comparatively moderate level commitment to responsible business practices.** Roche sets sales targets at the individual, division and company levels and incentives for agents are not solely based on sales volume. It incentivises both financial and non-financial goals. Roche commits to ensuring ethical interactions with healthcare professionals in its code of conduct. It discloses to the Index, but not publicly, the legitimate need for interactions with healthcare professionals and the limits on transfers of value to them. However, it declares that transfers of value to healthcare professionals (e.g., payments for exchanging scientific information or consulting) are made at fair market value. Finally, Roche 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.** Roche 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. Roche also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

**Roche publicly supports the Doha Declaration on TRIPS and Public Health.** However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Roche states that compulsory licensing should be considered on its own merits on a case-by-case basis.

**Fulfils some criteria across 2 processes for measuring and reporting patient reach.** For 1 process covering most of its products and most countries in scope of the Index, Roche provides the metrics and assumptions publicly and provided the underlying equation and limitations directly to the Index. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified for this process.

## RESEARCH & DEVELOPMENT RANK 8 SCORE 2.82

**8th place.** Roche performs above average in this Technical Area. It has some priority projects, but its pipeline is mostly focused on non-communicable diseases. The company has an access planning framework, with access plans in place for some of its late-stage pipeline candidates. Although Roche's access plans do have a relatively wide geographic scope, plans often focus on registration preparation. It does not publicly disclose disaggregated R&D investment data, but it performs strongly in R&D capacity building.

**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. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

**Average-sized priority R&D pipeline, compared to peers, with access plans in place for 75% (3/4) of the late-stage candidates.** Priority R&D pipeline of 13 projects, including 4 late-stage projects that target a priority gap. The company focuses on various priority areas, including hepatitis B, coronaviral diseases and other prioritised antibacterial-resistant infections. Of Roche's 4 late-stage candidates targeting a priority product gap, 3 (75%) have evidence of an access plan in place, mostly focusing on registration preparation, as well as equitable pricing and WHO prequalification. In addition, 3 diagnostics targeting a priority product gap were approved during the period of analysis.

**Large-sized pipeline, compared to peers, addressing other diseases in scope, with 23% (6/26) of late-stage projects covered by access plans.** The company has 26 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, Alzheimer's disease and lower respiratory infections. Roche provides evidence of access plans for 6 of its 26 late-stage projects, mostly focusing on registration preparation, equitable pricing and the inclusion of special populations in clinical trials. In addition, 1 diagnostic was approved during the period of analysis.

**Roche does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.** Furthermore, it does not disclose disaggregated R&D investment data to global health organisations.

**Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS).** One of these initiatives, the African Genomics Programme, aims to develop an open African-led biobank, through multiple collaborations, including African universities and research centres.

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**PRODUCT DELIVERY** RANK 12 SCORE 3.03

**12th place.** Roche performs above average in this Technical Area. The company demonstrates Best Practice by registering innovative products widely in LMICs. However, it does not engage in non-exclusive voluntary licensing. All its health system strengthening initiatives meet all Good Practice Standards, but its supply chain and manufacturing capacity building initiatives do not. It engages in supranational agreements for four products, providing access to countries outside these agreements. It implements access strategies and reports data on their outcomes; however, it lacks coverage in low-income countries.

**Roche registers newer products* in 30 countries in scope on average, more than any other company in scope.** It registers 67% of products assessed in at least 1 of the 10 countries with the highest disease burden, with one of its diagnostics registered in 8 of 10 countries with the highest burden. The company's trastuzumab/hyaluronidase-oysk (Herceptin Hylecta®), indicated for breast cancer, is most widely registered, totalling 63 countries in scope. The company reports engaging in several mechanisms to facilitate registration, for example, through the WHO Collaborative Registration Procedure (SRA-CRP) and for WHO Prequalified products.

**Supplies 4 products via supranational agreements.** Roche supplies 4 diagnostics for HIV and HPV-related cervical cancer testing assessed in this category via international partners, including the Clinton Health Access Initiative, the US President's Emergency Plan for AIDS Relief (PEPFAR), United States Agency for International Development, Unitaid and The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). For 3 of the 4 diagnostics, the company demonstrates access strategies for at least one country not eligible for such supply. Access strategies also include additional initiatives aimed at strengthening health systems, focusing on testing capabilities. The company shares outcomes of the supranational agreement and the non-eligible country's access strategies.

**Access strategies in place for healthcare practitioner (HCP)-administered products, supported by data to track outcomes and progress.** For the 5 products selected for analysis, all oncology medicines, Roche provides access strategy examples in UMICs and LMICs but not for any LICs. Roche demonstrates efforts to improve the accessibility and affordability of its products. For example, it negotiated a managed entry agreement based on a cost-sharing scheme for its oncology medicine, artezolizumab (Tecentriq®), to be included in the national fund in Tunisia (LMIC), which covers approximately 60-70% of the population. The rest of the population is covered by free medical assistance, whereby Roche provides the products for free. The company also provides evidence of health system strengthening initiatives in most of the strategies analysed. The company shares goals to expand access to its products, sometimes sharing more detailed future plans. For most examples assessed, the company shares the number of patients reached with its strategies and has approaches in place to track the strategies' outcomes and progress over time. For example, Roche provided evidence of increasing patients reached with artezolizumab from 2022 to 2024 through its strategy in Tunisia.

**Access strategies for self-administered products in limited countries, supported by some information on outcomes.** For 1 of the 4 medicines selected for analysis, Roche provides evidence of access strategies in UMIC and LMIC examples. For the other 3 products, it provides a UMIC example. The company did not provide any example in LICs. Roche provides evidence of considering country-specific barriers to access, as well as product affordability in its strategies. However, this is mainly limited to UMIC examples. In China (UMIC), 3 of the 4 products assessed achieved national reimbursement, which covers much of the population. In Peru (UMIC), in the absence of public reimbursement for its cancer medicine erlotinib (Tarceva®), Roche implements different support programmes, such as one for uninsured patients, covering both medicines and testing prices, and another supporting co-payment costs for insured patients. The company provides evidence of increasing patient reach over time and shares plans to advance some of its strategies.

**Roche publicly commits not to file for or enforce patents for all products in some countries in scope.** This applies to all least developed countries and LICs. Additionally, it does not file for or enforce patents for its antiretroviral HIV medicines in sub-Saharan Africa.

**Publicly discloses product patent status for countries in scope.** Like most peers, Roche publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

**Roche does not engage in non-exclusive voluntary licensing for products in scope.**

**Neither of the 2 manufacturing capacity building initiatives included for analysis meet all GPS.** In 1 initiative, Roche is transferring technology to Egyptian manufacturer Gypto Pharma for secondary packaging of oncology product bevacizumab (Avastin®). Roche shares know-how to support the partner in meeting requirements regarding technical capabilities, quality and safety, health and environmental standards.

**Two of the three supply chain capacity building initiatives included for analysis meet all GPS.** For example, Roche is continuing its Global Philanthropic Secondment Program in Namibia. So far, 14 Roche employees have gone to the Namibia University of Science and Technology to share knowledge on supply chains and logistics.

**All 5 health system strengthening initiatives included for analysis meet all GPS.** In 1 initiative, Roche is supporting the City Cancer Challenge Foundation to improve access to cancer care where essential healthcare services, diagnostics and treatments remain limited. Roche provides both financial and technical support, as well as sharing information about local health systems where the initiative operates.

**Roche has not entered into any new IP-sharing agreements, nor has it continued any existing agreements, with public research institutions or drug discovery initiatives to accelerate drug development.**

**Fulfils all criteria for ad hoc donations.** Roche 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. For example, in September 2023, Roche responded to aid requests from Morocco's ministry of health, by donating 4,000 vials of ceftriaxone (Rocephin®) to the earthquake-stricken country. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

**Fulfils all criteria for mechanisms to ensure continuous supply in LMICs.** For example, Roche is building a warehouse and distribution centre in Morocco where secondary packaging of 5 biological products will take place. The project aims to improve access for patients in the country.

**Roche has a policy for reporting substandard and falsified medicines in countries in scope.** It reports cases to national or local regulatory authorities, but it does not strictly specify the reporting timeframe. However, the company states that reporting typically occurs within 24 hours once a case is confirmed. Further, it reports that earlier reporting prior to the investigation's end is possible when visual inspection is sufficient for confirmation.

**Roche operates an inclusive business model that offers diagnostics** to 89 eligible countries.** The Global Access Programme (GAP), launched in 2014, allows governments, local healthcare facilities and international organisations to procure reduced-price hepatitis, TB, HPV and COVID-19 diagnostics. The model includes pricing for eligible organisations and governments, R&D for innovative collection methods and health worker training and education.



*Products that received their first marketing authorisation within the last 5 years.

**Through GAP, Roche also offers various reagents, controls, consumables and instruments used in molecular diagnostics.