

RANK	SCORE
<b>10</b>	<b>3.23</b>
9 (2021)	

# Roche Holding AG

Stock exchange: SIX • Ticker: ROG.SW • HQ: Basel, Switzerland • Employees: 100,920

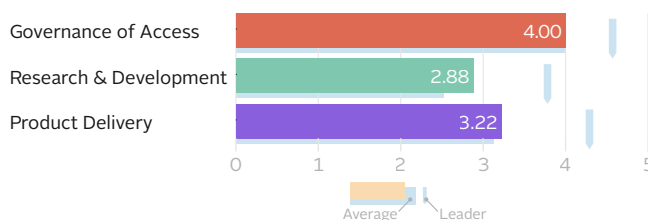
## PERFORMANCE IN THE 2022 INDEX

10<sup>th</sup> place. Roche ranks among the top ten companies of the Index. The company performs well in Research & Development, strengthening its performance in R&D access planning. The company has an average performance in Governance of Access, but its strategies for equitable access are below average for some products.

**Governance of Access:** 12<sup>th</sup> place. Roche has an average performance in this area. It has an access-to-medicine strategy integrated into its corporate strategy and publicly discloses outcomes of its access-to-medicine activities. However, it lacks a fraud-specific risk assessment as part of its compliance framework to mitigate the risk of non-compliance in countries in scope of the Index and a formal policy to limit transfers of values to healthcare professionals in countries in scope of the Index.

**Research & Development:** 8<sup>th</sup> place. Roche performs above average in this area. Roche has a structured access planning framework, with access plans in place for the majority of late-

How score was achieved



stage pipeline candidates. The company has a small-sized priority pipeline and has an average performance in R&D capacity building.

**Product Delivery:** 11<sup>th</sup> place. Roche has an average performance in this area. The company provides evidence of comprehensive access strategies for a subset of products, yet the focus is mostly on upper-middle and lower-middle income countries. Roche engages in high-quality supply chain capacity building and health systems strengthening initiatives, but its involvement in manufacturing capacity building is comparatively poor.

## OPPORTUNITIES FOR ROCHE

**Ensure all late-stage R&D projects have comprehensive access plans.** Roche has access plans in place for 90% of late-stage R&D projects. These predominantly focus on plans for registration filings. The company can expand existing plans beyond commitments to register in countries where it is conducting clinical trials to include more access components such as equitable pricing and licensing.

**Expand access strategies for oncology products.** Roche has seven on-patent medicines listed on the WHO Model List of Essential Medicines, including erlotinib (Tarceva®), a first-line treatment for lung cancer, and atezolizumab (Tecentriq®), indicated for multiple cancer types. Roche applies access strategies for erlotinib in upper-middle income countries, including an intra-country pricing strategy in Peru. It can apply similar equitable access strategies and non-exclusive voluntary licensing in lower-middle income countries and low-income countries with high burden of lung cancer such as Tunisia and Vietnam.

**Expand manufacturing capacity building activities to additional countries.** Roche is involved in technology transfer initiatives to regional manufacturers in Bangladesh, China and Algeria to improve availability of the company's oncology products. Through partnerships to build local manufacturing capacity, including technology transfers, Roche can improve availability of its products in more countries, such as Nigeria, Ghana and South Africa.

## CHANGES SINCE THE 2021 INDEX

- Expanded the Global Access Program in 2021 to include molecular PCR diagnostic tests for COVID-19.
- Expanded the proportion of access plans in its pipeline.
- Roche initiated a clinical trials framework, activating the first pharma sponsored oncology trial in East Africa.
- Suspended patents on tocilizumab (Actemra®/RoActemra®) in LMICs after the World Health Organization (WHO) recommended it as a treatment for severe COVID-19.
- Entered a partnership with The Global Fund to support LMICs in strengthening critical diagnostics infrastructure.
- Received WHO prequalification for HIV and HCV tests, and WHO guidelines now include cobas® MTB and cobas® MTB-RIF/INH tests.
- Launched a human papillomavirus (HPV) self-sampling solution, expanding cervical cancer screening options for patients living in areas with limited healthcare resources.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.

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:** Diagnostics and pharmaceuticals.

**Therapeutic areas:** Diabetes care, haemophilia A, immunology, infectious diseases, neuroscience, oncology and ophthalmology.

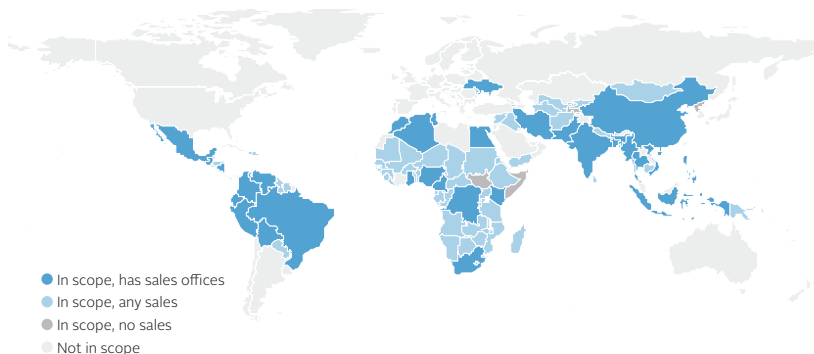
**M&A news:** Roche acquired GenMark Diagnostics in March 2021 for USD 1.8 billion.

Roche's products are sold in 93 out of 108 countries in scope of the Index. Roche has sales offices in 31 countries, and sells via suppliers and/or pooled procurement in an additional 62 countries.

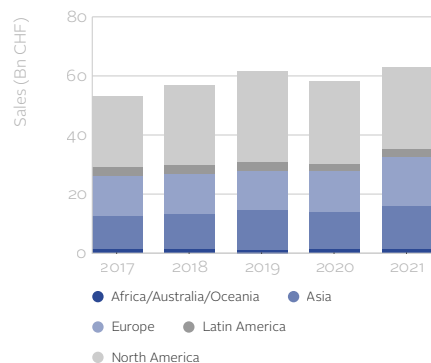
Sales by segment (2021) – in CHF

Pharmaceuticals	45.04 bn
Diagnostics	17.76 bn
<b>Total</b>	<b>62.80 bn</b>

Sales in countries in scope



Sales by geographic region



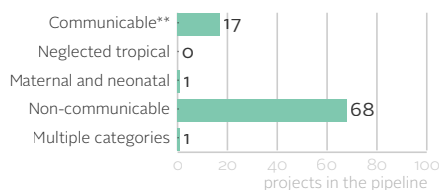
### SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

#### PIPELINE for diseases in scope

Roche has a total of 87 R&D projects in scope, with 17 of these projects targeting priority diseases. The other 70 R&D projects target other diseases in scope. In total, 14 of the 87 projects are diagnostic R&D projects. Of the projects targeting priority diseases the focus is on hepatitis B (five projects). Of the projects targeting other diseases in scope, the focus is on oncology (53).

Twenty R&D projects are in late-stage development that target either a priority disease (5) or address a public health need in LMICs (15).<sup>\*</sup> Evidence of access planning was in place for 90% of these projects: five targeting a priority disease and 13 addressing a public health need in LMICs.

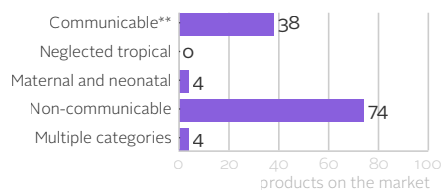
#### 87 projects in the pipeline



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

Roche has 29 medicines in scope, 23 of which are on patent, and 81 diagnostics. 41% of the medicines (12) are on the WHO EML. In addition, the company markets 13 platform technologies. The off-patent medicines target communicable diseases (CDs) (3) such as hepatitis C, malaria and lower respiratory infections and non-communicable diseases (NCDs) (4) such as cancer (2) and cardiovascular diseases (2). The on-patent medicines target NCDs such as cancer (15) and kidney diseases (2), and CDs such as HIV/AIDS and coronaviral diseases. The platform technologies target respiratory infections, diabetes, cancer and other diseases in scope of the Index.

#### 123 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	0	0	4	3	0	2	8	17
Addresses needs of LMICs <sup>*</sup>			1	5	9	1	1	17
Other projects in scope			23	11	14	1	4	53

#### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	7	16			23
off patent	5	1			6
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			81		81
Other <sup>†</sup>				13	13

<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.

# Roche Holding AG

## GOVERNANCE OF ACCESS

RANK 12

SCORE 4.00

**Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy.** Roche performs strongly. Its strategy is focused on understanding local barriers to access and covers all therapeutic areas the company is involved in. The highest responsibility for access lies directly with the board, namely with the Corporate Governance and Sustainability Committee.

**Provides evidence of financial and non-financial access-related incentives at the executive level.** Roche performs well. It incentivises its CEO, senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards.

**Publicly discloses outcomes of its access-to-medicine activities.** Roche performs strongly in transparency of access activities. It publicly discloses its 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, including its Global Access Programme, in a centralised manner within its Annual Report.

**Has an average performance in responsible promotional practices.** Roche's sales agents are not solely incentivised on sales volume targets. However, the company sets sales incentives at the individual level for agents. Roche has an internal tracking mechanism but 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. The company does not place limits on transfers of value to healthcare professionals, but reports setting remuneration in line with fair market value.

**Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.** Roche has an average performance, demonstrating evidence of some components looked for by the Index: country risk-based assessment, a contin-

uous 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. There is no evidence, publicly found or disclosed to the Index, of fraud-specific risk assessment. No breaches in countries in scope of the Index were publicly found in the period of analysis.

**Publicly supports the Doha Declaration on TRIPS and Public Health.** Roche publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, namely on the effectiveness of compulsory licensing to lower drug prices. There is evidence of industry association lobbying on intellectual property (IP) 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, Roche, like all other member companies in scope of the Index, is by default connected to this activity.

## RESEARCH & DEVELOPMENT

RANK 8

SCORE 2.88

**Access planning processes encompass all projects in the pipeline.** Roche has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope of the Index.

**An average-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (5/5) of the late-stage candidates.** Roche has 17 projects including five late-stage candidates in its pipeline that target a priority product gap. These focus mostly on hepatitis B and coronaviral diseases. Roche has access plans in place for all five late-stage priority candidates. These plans mainly concern registration preparation in countries in scope of the Index. Notably, the access plan for tocilizumab (Actemra®/RoActemra®) for the treatment of COVID-19 uses a multifaceted approach that considers availability, affordability and supply. The plan includes registration preparation in countries in scope of

the Index, a new pricing policy, WHO prequalification, patent waivers in LMICs, product donations and scaling up production capacity to meet demands.

**Many projects address a public health need in LMICs,\* with 87% (13/15) of late-stage projects covered by access plans.** In this analysis, Roche has 15 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. Most target cancer or Alzheimer's disease. Roche provides evidence of access plans for 13 of these projects. These plans mostly relate to an intention to register in countries where Roche is carrying out clinical trials.

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

**Two of the three R&D capacity building initiatives included meet all Good Practice Standards.** Roche's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all Good Practice Standards (GPS) for this indicator. For example, Roche builds R&D capacity by educating lab researchers through its Fondation Roche Recherche en Afrique scholarship programme. This initiative provides scholarships to students in Côte d'Ivoire to increase the number of skilled medical laboratory technicians and meets all GPS.

\*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 11

SCORE 3.22

**Public commitment not to enforce patents in countries in scope.** Roche publicly pledges to neither file for nor enforce patents in all Least Developed Countries and LICs within the scope of the Index. Roche does not file nor enforce patents for its antiretroviral HIV medicines in sub-Saharan Africa.

**Publicly discloses information on patent status.** Like most of its peers, Roche discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Roche's disclosure includes information about patents, patent number and jurisdiction.

**Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers.** Roche does not report on any new IP-sharing agreements with public 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.

**No use of licensing agreements.** Roche does not engage in voluntary licensing agreements for products in scope of the Index.

**Filed to register new products in 22 countries in scope on average.** Roche has filed for registration one of its newest products in eight of the top ten high burden countries. This product, Elecsys® Chagas, used for diagnosis and screening of Chagas disease, has been filed for registration in 15 countries in scope of the Index. The majority of Roche's products considered for analysis have not been filed for registration in LICs.

**Has access strategies for its supranationally procured products in scope of this analysis.** Roche performs below average in securing access for products procured supranationally. The company supplies three products assessed via its Global Access Program (GAP), developed in consultation with international partners including CHAI, PEPFAR, USAID, UNITAID and the Global Fund. Roche did not provide examples of how access was secured for countries not eligible for the GAP. However, Roche has been expanding the GAP by including new diagnostics for HPV-related cervical cancer, tuberculosis and hepatitis in 2019 and molecular PCR diagnostic tests for COVID-19 in 2021. The company demonstrated expansion of patient reach: to date over 11 million children have been tested for HIV with Roche tests.

**Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis.** Roche shows average performance in this area. The company provides examples of access strategies in both UMICs and LMICs for four of the five products

assessed. Examples of access strategies in LICs were not provided. Roche makes efforts to reach additional patients using patient assistance programmes (PAPs). For example, Roche applies differential pricing for pertuzumab (Perjeta®) in Egypt based on the patients' ability to pay, and it implements both pricing and non-pricing support to out-of-pocket patients through a PAP while strengthening the health systems with capacity building initiatives. Roche provides evidence of how patient reach has been increased through the approaches used, reporting that patient reach has more than doubled in 2021.

**Has access strategies for its self-administered products for few countries in scope of this analysis.** Roche performs below average in this area. The company provides examples of access strategies which consider payers' affordability in UMICs and LMICs for one of the four products assessed: alectinib (Alecensa®), a cancer drug. This included efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, the company has implemented a four-tiered pricing strategy for alectinib in the Philippines, the ALIVE programme, based on the country's profile and patients' economic status. In addition, the company created a PAP to reduce the out-of-pocket costs for patients. Roche has further initiatives to support medicine access such as deferred payment schemes and capacity building initiatives to strengthen the healthcare system. Evidence of patient reach increase is provided.

**None of the manufacturing capacity building initiatives included for analysis meet all Good Practice Standards.** Roche's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In one of the included initiatives starting in 2018, Roche built manufacturing capacity by transferring technology for secondary packaging of bevacizumab (Avastin), trastuzumab (Herceptin®) and rituximab (MabThera®) in Algeria.

**Three of the four supply chain capacity building initiatives included meet all Good Practice Standards.** Roche's performance is above average 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, the Global Philanthropic Secondment Program provides the mechanism to share Roche employee expertise with NGOs that are helping to improve global health and education, including the topic of supply chain, logistics and project management.

**All five health systems strengthening initiatives included for analysis meet all Good Practice Standards.** Roche 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, Project ECHO® (Extension for Community Health Outcomes) aims to help broaden access to best practice cancer treatment in LMICs by training and mentoring healthcare personnel in underserved areas.

**Has engaged in scaling up three inclusive business models but has not shown evidence of its involvement in piloting any new inclusive business models that meet all inclusion criteria.**

Roche performs average 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. Project TRACMA aims to solve access hurdles of breast cancer patients in Angola and provide therapies to the patients who can benefit from them.

**Performs above average in terms of ensuring continuous supply of medicines in LMICs.** Roche 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.** Roche has a policy for reporting SF medicines to relevant health authorities, but does not strictly specify the reporting timeframe. Roche, however, states that reporting typically occurs within 24 hours once a case is confirmed. Earlier reporting prior to the end of the investigation is possible when visual inspection is sufficient for confirmation.

**Donates in response to expressed need and monitors delivery.** Roche has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

**Has no long-term donation programmes for neglected tropical diseases (NTDs) or malaria that are eligible for analysis under this indicator.** Roche is not engaged in any structured donation programmes for NTDs or malaria where elimination, eradication or control goals are possible and that are eligible for analysis under this indicator.