| RANK | SCORE |
|------|-------|
| 10 ▲ | 2.38 |
| 19 (2016) | |

# Roche Holding AG

Stock Exchange: SIX Swiss Exchange • Ticker: ROG • HQ: Basel, Switzerland • Employees: 93,734

## PERFORMANCE

Roche lands at 10th, rising 9 places since the 2016 Index and 2 places compared with 2014. Roche focuses on access to cancer care and improvements in performance can in part be attributed to the inclusion of cancer in scope.

**Management:** Rises 17 places to 2nd due to a refreshed access-to-medicine strategy governed by board members, and an innovative global access programme aimed at access to HIV diagnostics.

**Compliance:** Holds steady at 4th through ensuring third-party compliance with its standards, and rewards for sales agents are not solely based sales targets.

**R&D:** Rises 5 places to 14th but places in third quartile as it lacks a clear process for the development of access plans for its late-stage projects.

**Pricing:** Rises 12 places to 8th due to an improvement in the range of products that have equitable pricing strategies, extended to further countries.

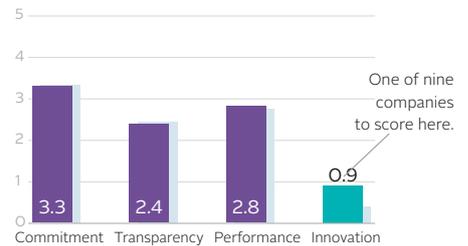**Patents:** Falls 6 places to 17th. Overtaken by peers in IP sharing, with no current engagement in licensing.

**Capacity:** Rises 10 places to 9th with multiple capacity building initiatives with a focus on cancer control.

**Donations:** Rises one place to 11th. Engages in three structured donation programmes focused on cancer, including for trastuzumab (Herceptin®).
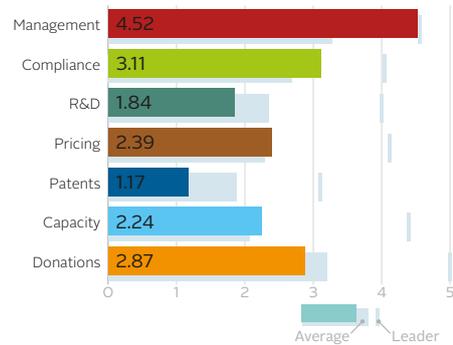
## OPPORTUNITIES

**Improve access plans for R&D projects during development.** Roche can improve its process to develop access plans by expanding this process to all projects for diseases in scope. Currently, Roche considers access in an *ad hoc* manner and utilises a general market access approach for its R&D projects without tailored access plans for diseases and countries in scope. Considering the unique barriers to access that affect those living in low- and middle-income countries, Roche can help ensure more patients globally can access products as soon as possible following market approval.

**Build on strong capacity building initiatives.** Breast cancer has the highest incidence of all cancers in countries in scope. Roche's Partnership to Improve Breast Cancer in Kenya is focused on increasing awareness and screening, improving diagnosis and treatment, and training healthcare professionals. This initiative meets all good practice standards. It is working in line with Kenya's national strategies to improve non-communicable disease (NCD) care, including breast cancer. Roche can identify other countries with national strategies for NCD or cancer control and partner to improve breast cancer care.

**Expand access through increasing supply.** Roche can identify generic medicine manufacturing partners for the non-exclusive voluntary licensing of products for high-burden diseases. Products could include rituximab (MabThera®) listed on the 2017 WHO Model List of Essential Medicines (WHO EML) for diffuse large B-cell lymphoma, chronic lymphocytic leukaemia, and follicular lymphoma. This can be facilitated through the newly expanded Medicines Patent Pool (MPP) mandate to include patented medicines on the WHO EML in its patent pooling and voluntary licensing strategy.

**Focus expertise in diagnostic devices to address more priority R&D product gaps.** Roche has an extensive portfolio of diagnostic devices and the largest number of diagnostic candidates in the pipeline. It can use its expertise to expand its diagnostic development to address more identified priority R&D product gaps in priority areas where it is currently active or has been active (HIV, viral hepatitis B and C and tuberculosis) as well as expanding its arsenal of diagnostic tests for specific pathogens, such as those responsible for diarrhoeal diseases, including *V. cholerae* and *Shigella* species.

### Performance by technical area

| Area | Score |
|------|-------|
| Management | 4.52 |
| Compliance | 3.11 |
| R&D | 1.84 |
| Pricing | 2.39 |
| Patents | 1.17 |
| Capacity | 2.24 |
| Donations | 2.87 |

Average  Leader

### Performance by strategic pillar

| Commitment | Transparency | Performance | Innovation |
|------------|--------------|-------------|------------|
| 3.3 | 2.4 | 2.8 | 0.9 |

One of nine companies to score here.

### CHANGE SINCE 2016

- Refreshed its access-to-medicine strategy with clear targets through its Access Planning Framework, which focuses on ensuring availability by working on awareness, diagnosis, healthcare capacity and funding.
- Partnered with the government of Niger State, Nigeria to provide high-quality drugs and free treatment for breast cancer patients and build capacity for prevention and care.
- Joined Access Accelerated with multiple initiatives focused on cancer care. It has also committed to measure impact and share results publicly via Access Observatory.
- Participates in Brazil's Partnerships for Productive Development to transfer production of biologic products, and provides training as part of the transfer.
- Launched in August 2016, a five-year partnership with the Kenya Ministry of Health in order to improve care and treatment for breast cancer.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.

**PIPELINE** *for diseases and countries in scope*

**Comparatively large pipeline:** 100 R&D projects for diseases in scope (89 medicines; 11 diagnostics).
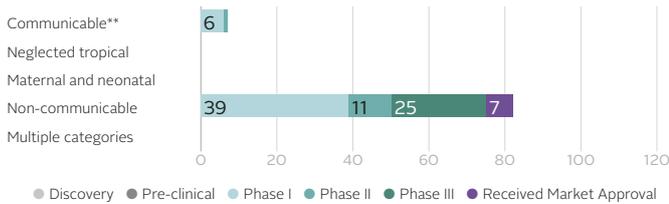**Clinical candidates:** 82, including a novel inhibitor for the treatment of influenza and five Phase I medicines for the treatment of hepatitis B virus.
**Regulatory approvals:** 7, including atezolizumab (Tecentriq®) for the treatment of bladder and lung cancers.
**R&D focus:** non-communicable diseases (cancer and diabetes mellitus) and communicable diseases (viral hepatitis B).
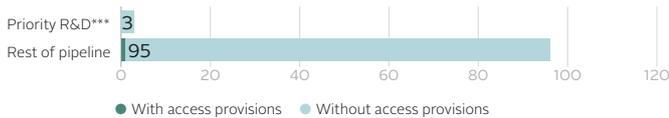**Access provisions:** for 2 projects, one of which has an equitable pricing commitment and the other with registration and supply strategies.

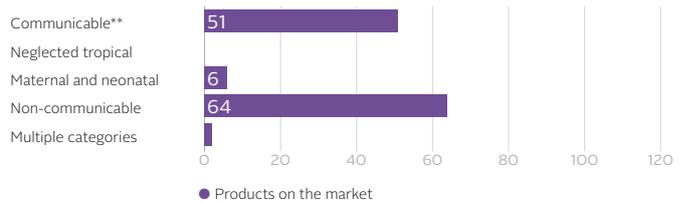**PORTFOLIO** *for diseases and countries in scope*

**Comparatively large portfolio:** 123 products for diseases in scope (90 diagnostics; 20 medicines; 13 platform technologies).
**Portfolio focus:** non-communicable diseases (cancer and ischaemic heart disease) and communicable diseases (viral hepatitis B and C and HIV/AIDS).
**Essential medicines:** 65% of Roche's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
**First-line treatments:** 55% of Roche's medicines have first-line indications for diseases in scope.

**Projects in the pipeline: 100\***

| | |
|---|---|
| Communicable** | 6 |
| Neglected tropical | |
| Maternal and neonatal | |
| Non-communicable | 39  11  25  7 |
| Multiple categories | |

● Discovery  ● Pre-clinical  ● Phase I  ● Phase II  ● Phase III  ● Received Market Approval

**Products on the market: 123**

| | |
|---|---|
| Communicable** | 51 |
| Neglected tropical | |
| Maternal and neonatal | 6 |
| Non-communicable | 64 |
| Multiple categories | |

● Products on the market

Roche is one of only five companies in the scope of the Index developing diagnostics for diseases in scope. These include diagnostics for human papilloma virus (HPV), HIV/AIDS, *C. difficile* and the priority pathogen *S. aureus*.

Roche's portfolio includes products such as the cobas® Plasma Separation Card which is used for HIV plasma viral load testing and keeps blood samples intact even in areas of extreme heat and humidity for transport.

**Projects for R&D priority targets with access provisions: 0**

| | |
|---|---|
| Priority R&D*** | 3 |
| Rest of pipeline | 95 |

● With access provisions  ● Without access provisions

**Essential medicines with first-line indications: 9**

| | |
|---|---|
| WHO EML | 9  4 |
| Non-EML | 5 |

● First-line products  ● Other

Of Roche's 100 R&D projects, two are supported by access provisions: e.g., Perjeta® for the treatment of breast cancer has a commitment for equitable pricing in all LMICs. Two of its 44 late-stage projects have provisions.

75% of Roche's medicines are listed on the WHO EML and/or as first-line treatments: e.g., trastuzumab (Herceptin®), oseltamivir (Tamiflu®) and epoeitin beta (NeoRecormon®).

**BUSINESS CONTEXT**

**Two business units:** Pharmaceuticals and Diagnostics. Its pharmaceutical business has five therapeutic areas (oncology; infectious diseases; immunology; ophthalmology; and neuroscience). Its diagnostics business has four business units (Centralised and Point of Care Solutions, Diabetes Care, Molecular Diagnostics and Tissue Diagnostics).
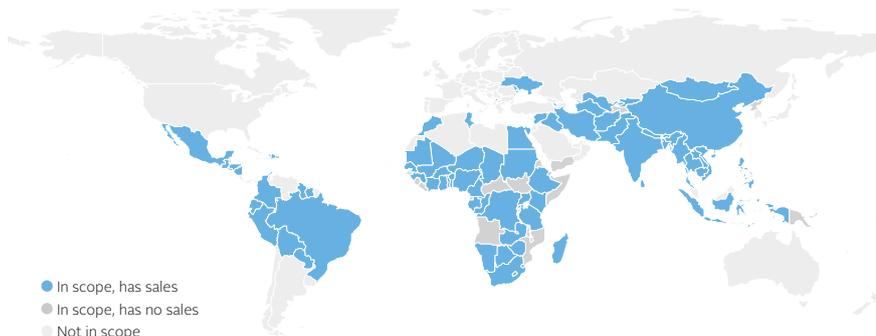**M&A news:** Activity includes the 2018 acqui-sition of Ignyta, a biotechnology company focused on oncology therapeutics; merger with Foundation Medicine, which develops and markets genomic analysis diagnostics for cancer.
**Presence in emerging markets:** In 2018, Roche reports sales in 77 countries in scope; 11 less than in the 2014 Index. It reports that more than 25% of its sales in 2017 came from Asia and Latin America.

**Sales by segment (2017) - CHF**

| | |
|---|---|
| Pharmaceuticals | 41,220 MN |
| Diagnostics | 12,079 MN |
| | |
| Total | 53,299 MN |

**Sales in countries in scope**



● In scope, has sales
● In scope, has no sales
● Not in scope

**Sales by geographic region**



● Africa/Australia/Oceania  ● Asia
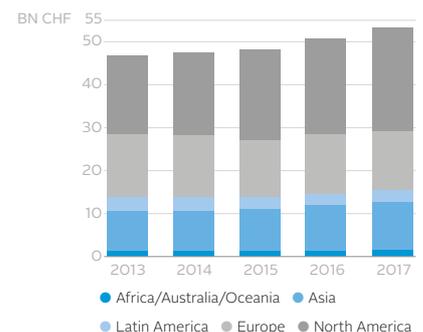● Latin America  ● Europe  ● North America

Statistics relate only to diseases and countries in scope.

*Figure excludes 11 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
***See Appendix IV for definition.

# Roche Holding AG

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT
RANK 2     SCORE 4.52

**Has a strong access-to-medicine strategy with board-level responsibility.** Roche is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The strategy centres around identifying access-related issues with local stakeholders and developing country-specific plans using its Access Planning Framework. This framework is focused on four areas: awareness; diagnosis; healthcare capacity; and funding. The highest level of responsibility for access sits with a board-level committee.

**Financial and non-financial access-related incentives to reward employees.** Roche performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include annual performance-related goals, and internal recognition and awards. Senior management has a separate incentive that supports the company's long-term access-oriented objectives.

**One of 16 companies working on impact measurement.** Roche measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments and performance information. For example, for its Patient Access Dashboard initiative, Roche reports having increased access to standard of care treatment for blood cancers and breast cancer in 14 low- and middle-income countries. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

**Discloses who it engages with, incorporates local perspectives into strategies.** Roche publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by conducting a materiality assessment and an engagement activity. Local stakeholder perspectives are incorporated into the development of its access strategies. However, it does not publicly share its policy for ensuring responsible engagement.

### MARKET INFLUENCE & COMPLIANCE
RANK 4     SCORE 3.11

**Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards.** Roche has a code of conduct relating to ethical marketing and anti-corruption, and provides continuous compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities relating to diversity, sustainability and the environment.

**Internal control framework meets some Index criteria.** Roche's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has a monitoring system in place to track compliance, and auditing processes. It also has procedures to segregate duties, so that decisions are checked by another party. It does not, however, demonstrate evidence of having fraud-specific risk assessment.

**Above average transparency regarding access-related practices.** Roche publicly discloses its policy positions on access-related topics (e.g., its position on counterfeit medicine and human rights). It does not disclose its political contributions in countries in scope. It publicly discloses its financial support and membership of relevant organisations to access, and is the only company in scope to disclose its policy for managing conflicts of interest with these institutions. The company also discloses its policies for responsible engagement. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

### RESEARCH & DEVELOPMENT
RANK 14     SCORE 1.84
PROJECTS: 100   IN CLINICAL DEVELOPMENT: 82

**Publicly commits to R&D to meet public health needs.** Roche has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on data from external sources like WHO related to global disease burden. It lacks time-bound strategies for completing R&D projects for diseases in scope. Roche has one of the largest pipelines in the Index with 100 pro-

jects. For diseases in scope where priorities exist, Roche is active in five projects; three of these target priority R&D gaps.

**Access provisions in place for 5% (2/44) of late-stage candidates.** Roche does not have a clear process in place to develop access plans during R&D. Instead, Roche considers access on a case-by-case basis. In general, Roche develops access plans for these R&D projects in Phase I or II of clinical development. To date, Roche has project-specific access provisions in place for two of its late-stage R&D projects. Of these, one is being conducted in partnership with Shionogi Inc.

**Public policy to ensure post-trial access; commits to registering trialed products.** Roche has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Roche commits to registering it in all countries where clinical trials for the product have taken place.

### PRICING, MANUFACTURING & DISTRIBUTION
RANK 8     SCORE 2.39
PRODUCTS: 123
COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 6

**Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope.** Roche does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. This does not explicitly apply to future products. It also commits to implementing intra-country pricing strategies, albeit to only some of its products.

**Many new products in scope filed for registration in the majority of relevant priority countries.** Roche has filed 70% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration information for any of its products.

**5% of products have equitable pricing strategies targeting priority countries.** Roche's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 5% of its products for diseases in scope. These strategies apply to an average of 84% of priority countries. Some of these strategies apply both inter- and intra-country pricing; these take into account an average of one and three socioeconomic factors, respectively.

**Has both globally consistent recall guidelines for countries in scope and processes to track products.** Roche has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

## PATENTS & LICENSING
### RANK 17    SCORE 1.17

**Publicly discloses detailed information on patent statuses.** Like most of its peers, Roche publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

**No use of non-assert or licensing arrangements.** Roche does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

**Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements.** Roche reported existing agreements with product development partnerships, such as the TB Alliance. During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

**Public commitment not to enforce patents in countries in scope.** Roche commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries. The company also do not file or enforce patents for any of its antiretroviral HIV medicines in sub-Saharan African countries.

## CAPACITY BUILDING
### RANK 9    SCORE 2.24

**10 initiatives included for evaluation.** Roche has 10 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Roche submitted 21.

**Focused on supporting pharmacovigilance and strengthening health systems.** Roche has initiatives that meet inclusion criteria in all five areas of capacity building. Most of these initiatives are focused on pharmacovigilance and health system strengthening. These initiatives are most active in Africa.

**Two initiatives meet all applicable good practice standards:**
- Strengthening the Supply Chain in sub-Saharan Africa
- Partnership to Improve Breast Cancer Care in Kenya

Roche's remaining included initiatives typically have goals in place, but fall short on monitoring progress and outcomes.

**Timely approach to reporting substandard or falsified medicines to relevant authorities.** Roche provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days).

## PRODUCT DONATIONS
### RANK 11    SCORE 2.87
### STRUCTURED DONATION PROGRAMMES: 3

**Has policy for responding to emergencies or humanitarian crises.** While Roche did not make any *ad hoc* donations during the period of analysis, it has policies in place to respond directly to need, which are aligned with international guidelines. It has plans in place to ensure products are rapidly made accessible and to track the delivery of the product until received by end user.

**Three donation programmes covering diseases and countries in scope.** Roche's programmes are focused on non-communicable diseases (NCDs), namely cancer. All three programmes are carried out in collaboration with partners such as local ministries of health. Its breast cancer programmes supply trastuzumab (Herceptin®) in China, Pakistan and the Philippines. The programme in China began in 2011 with Roche reporting that nearly 20,000 breast cancer patients benefited from trastuzumab (Herceptin®) in 2016.

**Ensures long-term access through transition planning.** Roche has transition plans in place for its trastuzumab (Herceptin®) donation programme to ensure ongoing access for patients once the programme ends. The company will work with both national and local government units, health institutions and other stakeholders to ensure public reimbursement for trastuzumab (Herceptin® ) so that patients can obtain it via the public health system. This will involve mobilising alternative sources of funding for cancer patients, such as the development of private health insurance for cancer.

## BEST PRACTICES

### Leading platforms to track access activities
GLOBAL
Systems that enable them to track how local access strategies are implemented, and how activities progress.

### Comprehensive overview of stakeholder engagement
GLOBAL
Only company in scope to share publicly, via its website, a clear overview of the way it engages with each specific stakeholder.

## INNOVATIVE PRACTICES

### Systematic approach to identify access challenges
GLOBAL
A comprehensive Access Planning Framework Patient Access Dashboard to determine current access levels in countries, and how its initiatives contribute to access.

### Global Access Program provides better access to diagnostic testing for HIV/AIDS in 82 countries
GLOBAL
Combining equitable pricing policies with capacity building and diagnostics R&D.