PERFORMANCE IN THE 2021 INDEX

9th place. Roche has an average performance. The company performs well in filing for registration and transparency of access activities, publicly disclosing its commitment and outcomes, but performs less strongly in R&D.

Governance of Access: 6th place. Roche performs well in this area. It has an access-to-medicine strategy integrated into its corporate strategy and publicly discloses commitments and outcomes of its access-to-medicine activities. The company provides access-related incentives at the executive level, but not for the CEO.

Research & Development: 9th place. Roche’s performance is average in this area. The company has a structured process to develop access plans during R&D for all projects in the pipeline. Yet, it has a small R&D priority pipeline compared to peers and few of its late-stage projects that address a public health need in LMICs are covered by an access plan.

Product Delivery: 12th place. Roche is a middle-performing company in this area. The company provides evidence of access strategies, but they are focused on middle-income countries. It registered some of its new products in the majority of high burden countries. Although engaged in capacity building initiatives, most initiatives did not meet all Good Practice Standards.

OPPORTUNITIES FOR ROCHE

Expand access strategies for oncology products to LICs. Roche has six on-patent medicines listed on the 2019 WHO Model List of Essential Medicines (WHO EML), including erlotinib (Tarceva®) and trastuzumab (Herceptin®), two first line treatments for lung and breast cancer, whose incidence is the highest in countries in scope, using mechanisms such as voluntary licenses. Roche implemented an intra-country pricing strategy for erlotinib (Tarceva®) in Peru. Roche could apply similar intra-country pricing strategies in LMICs with high burden of lung cancer such as Vietnam, Moldova, Tunisia and Myanmar. For healthcare practitioner-administered oncology treatments, Roche could apply access strategies in those countries where the cancer burden is growing.

Expand technology transfer initiatives to other geographic areas, including sub-Saharan Africa. Roche could expand the geographic scope of its technology transfers beyond China and Brazil.

Expand the Global Access Program to include Covid-19. The Global Access Program was launched in 2014 in partnership with UNAIDS, CHAI, PEPFAR and the Global Fund to facilitate access to viral load testing. Roche could include diagnostics for SARS-CoV-2 in this programme to facilitate access to testing in countries in scope.

Expand access planning to include equitable pricing and apply to all R&D projects. Roche has an access plan in place for its one late-stage priority R&D project and for 21% of R&D projects identified as having a clear public health benefit in countries in scope. These plans prioritise filing for registration and a differential pricing strategy for some products. Roche should apply its access planning process (e.g. registration and tiered pricing strategies) to all late-stage R&D projects, especially its diagnostics such as malaria diagnostics and HPV diagnostics.

CHANGE SINCE THE 2018 INDEX

- Developed and launched a tracking tool, the Roche Access Index, to measure progress on global patient access.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Joined the COVID-19 Therapeutics Accelerator.
- Partners with Gusun, China to produce biotech products locally with first product bevacizumab (Avastin®).
- Established new partnerships on supply chain (cold chain) and training programmes with governments of Kenya and Sudan.
- Expanded NJIA aimed at leadership development for cervical cancer to include India.
- Develops centres of excellence in selected sites focused on the African patient access and representation in key clinical trials for oncology, haemophilia and neurology.
- Expanded the Global Access Program beyond HIV to include tuberculosis, hepatitis B and C and human papillomavirus (HPV).
SALES AND OPERATIONS

Business segments: Pharmaceuticals; Diagnostics
Therapeutic areas: Oncology; Immunology; Neurosciences; Ophthalmology; Haemophilia A; Infectious diseases; Diabetes care
Product categories: Innovative medicines; Diagnostics

M&A news: Acquired Spark Therapeutics (gene therapy) for USD 4.3 billion in 2019; acquired Promedior (fibrotic diseases), Stratos Genomics

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SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope
Roche has a total of 62 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 12 projects. The other 50 R&D projects target other diseases in scope. In total, 15 of the 62 projects are diagnostic R&D projects. Of the projects targeting priority diseases, including five diagnostic projects, the therapeutic focus is on hepatitis B (6 projects).

Of the projects targeting other diseases in scope, the focus is on oncology (33). 20 R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (19).* Evidence of access planning was in place for 25% of these projects: 1 targeting a priority disease and 4 addressing a public health need in LMICs.

62 projects in the pipeline

Breakdown of projects*

<table>
<thead>
<tr>
<th>Category</th>
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<td>Maternal and neonatal</td>
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<td>Non-communicable</td>
<td>1</td>
</tr>
<tr>
<td>Multiple categories</td>
<td>49</td>
</tr>
</tbody>
</table>

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PORTFOLIO as selected for analysis by the Index
Roche has 27 medicines in scope, 19 of which are on patent. 48% of these medicines (13) are on WHO’s EML. In addition, the company markets 93 diagnostics and 12 platform technologies. The off-patent medicines target both non-communicable diseases (NCDs) such as cardiovascular diseases (2) and cancer and communicable diseases (CDs) such as hepatitis C (2). On the off-patent medicines mainly target cancer (13) and other NCDs. In addition, two products target CDs: HIV and lower respiratory tract infections. The diagnostics in scope are for NCDs such as diabetes (5) and cancer (37), for CDs such as viral hepatitis (18) and for maternal and neonatal health conditions such as maternal sepsis (3). The 12 platform technologies target both NCDs (4) such as cancer (2) and CDs (8) such as HIV (2). Access strategies were analysed for 13 products on Roche’s portfolio – supranationally procured (4) or nationally procured HCP-administered (5) and self-administered products (4).

132 products as selected for analysis by the Index†

Breakdown of products

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*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, 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.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

***Diagnostics for Covid-19 are not listed on the 2019 WHO Model List of Essential In Vitro Diagnostics.
†Other includes platform technologies. See Appendix I for definitions.
‡Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria. 
#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.
Roche Holding AG

### GOVERNANCE OF ACCESS

<table>
<thead>
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<tbody>
<tr>
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</table>

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Roche performs strongly. It has a strategy focused on understanding local barriers to access. The strategy 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 of the Board of Directors.

Provides evidence of financial and non-financial access-related incentives at the executive level. Roche performs well. It incentivises its senior executives and in-country managers to take action on access to medicine as part of their annual bonus plan. There is no evidence, however, that the CEO is also incentivised toward access goals.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Roche performs well in transparency regarding access activities. It publicly discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example its Global Access Programme, and through the IFPMA Global Health Progress platform.

Has an average performance in responsible promotional practices. Roche’s sales agents are not solely incentivised on sales volume targets. The company sets sales incentives at the individual level for agents. Roche has an internal tracking tool but does not publicly disclose information related to transfers of values to healthcare professionals (e.g., payments for attending events or promotional activities), unless required by local regulations.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Roche has an average performance, demonstrating some of the components looked for by the Index: country risk-based assessment, audits (both internal and external), covering third parties and in all countries where it operates, a continuous system to monitor activities and formal processes in place to ensure third-party compliance with company standards. It does not, however, have a fraud-specific risk assessment in place.

Publicly supports the Doha Declaration on TRIPS and Public Health. Roche publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely on the use of compulsory licensing. There is no evidence of a policy to dissent from industry association positions on IP.

### RESEARCH & DEVELOPMENT

<table>
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Access planning processes encompass all projects in pipeline. Roche has a structured process in place to develop access plans on a case-by-case basis during R&D. In general, Roche begins developing access plans for R&D projects in Phase III of clinical development. The process is for both its in-house and collaborative R&D projects.

A small-sized priority R&D pipeline compared to its peers, with access plans in place for one of the late-stage candidates. Roche has 12 projects including one late-stage candidate in its pipeline that target a priority product gap. The company focuses mostly on viral hepatitis (B and C). There is evidence of an access plan for Roche’s late-stage candidate targeting a priority product gap. This plan for tocilizumab to treat COVID-19 includes plans to register the product, apply an equitable pricing approach whereby prices are linked to the country’s ability to pay (i.e., GNI per capita) and increase sufficient supply.

Many projects address a public health need in LMICs*, with 21% of these projects covered by access plans. In this analysis, Roche has 19 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 and/or are first-in-class molecules. Most target cancer. Roche provides evidence of access plans for four of these projects. These plans prioritise registration in LMICs and a differentiated pricing strategy will be applied to some products.

Public policy to ensure post-trial access; commits itself to registering trialled products. Roche has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy applies on a case-by-case basis. Once a product is approved, Roche commits itself to registering it in all countries where clinical trials for the product have taken place. This policy considers affordability for the wider population in the country where the trial(s) took place.

One R&D capacity building initiative meets all Good Practice Standards. Roche has an average performance in this indicator. The company submitted four initiatives, of which two were included for analysis. One initiative met all Good Practice Standards. For this initiative, Roche is building clinical R&D capacity in clinical trial sites in seven sub-Saharan African countries, with a focus on site training and increasing African patient access to, and representation in, key clinical trials. The initiative takes place in South Africa, Ivory Coast, Tanzania, Ghana, Nigeria, Kenya and Uganda and areas of focus include oncology, haemophilia and neurology.

### PRODUCT DELIVERY

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<tbody>
<tr>
<td>12</td>
<td>2.92</td>
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</table>

Public commitment not to enforce patents in countries in scope. Roche publicly pledges to neither file for nor enforce patents. This commitment applies in all Least Developed Countries and low-income countries. The company also does not file for or enforce patents for any of its antiretroviral HIV medicines in sub-Saharan African countries.

Publicly discloses detailed information on patent status. Like most of its peers, Roche discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

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

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

Filed to register some new products in the majority of high burden countries. Roche has filed 30% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of coun-
tries with the highest burden of disease). For example, the oncology medicine atezolizumab (Tecentriq®) has been filed for registration/registered in 17 high burden countries in scope, including El Salvador and Myanmar.

Has access strategies for some supranationally procured products in scope for this analysis. Roche performs below average in securing access for products procured supranationally. The company did not provide examples of how access was secured for countries not eligible for supranational supply in three of the four products selected for analysis in this indicator. However, for valganclovir (Valcyte®), all countries in scope are eligible to procure it supranationally through the Medicines Patent Pool supply agreement.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Roche performs above average in this area. The company provides examples of access strategies which consider affordability in both UMICs and LMICs for three of the five products assessed. It makes efforts to reach additional patients using patient assistance programmes. For example, in India, for the oncology medicine, atezolizumab (Tecentriq®), Roche applies intra-country pricing strategy through a patient assistance programme that assess patient income and reimbursement status and offers tailored payment schemes to increase access, while strengthening the health system by enhancing diagnostics capacity. The company increased access by 20% in 2020. Roche is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope of this analysis. Roche performs below average in this area. The company provides examples of access strategies which consider affordability in UMICs and LMICs for one of the four products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in Peru, for the oncology medicines portfolio, the company uses a staggered payment fee for private sector clinics. Roche is able to provide evidence of how patient reach has been increased through the approaches used.

Two manufacturing capacity building initiatives included for evaluation. Roche performs below average in this indicator. The company submitted the two initiatives, which both met all criteria for inclusion. The initiatives, which included technology transfers of biotechnology and biological products in China and Brazil, respectively, did not meet all Good Practice Standards®, as Roche did not sufficiently demonstrate that the initiative is measuring outcomes.

Four supply chain capacity building initiatives included for evaluation. Roche performs below average in this indicator. Roche submitted five initiatives, of which four met all criteria for inclusion. For example, through the Global Philanthropic Secondment Programme, Roche is sharing company and employee knowledge on supply chain and logistics management at the Namibia University of Science and Technology. None of the initiatives submitted by the company met all Good Practice Standards®, as Roche does not sufficiently demonstrate how the initiatives have long-term supply chain capacity aims.

Four health system strengthening initiatives meet all Good Practice Standards. Roche performs above average in this indicator. The company submitted the maximum of five initiatives, of which four were included for analysis and met all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, the NJIA initiative in Tanzania and India aims to enhance the prevention and early diagnosis of cervical cancer through leadership development amongst community health workers. Since its launch in 2015, NJIA-trained health workers have screened 6,792 eligible women in the Kagera region in Tanzania as part of NJIA activities, which indicates an increase of at least an average of 539% compared to the five years before the program started.

Has engaged in the development and implementation of scaled up inclusive business models. Roche performs above average when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has scaled up its Global Access Programme running in 82 countries (which aimed to provide better access to diagnostic testing for HIV/AIDS) to include other diseases: hepatitis B and C, human papilloma virus (HPV) and tuberculosis.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Roche performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in scope of the Index. For example, the API manufacturing of their core medicines is spread across different geographic regions to protect against local and/or regional incidents. To overcome challenges related to timely and accurate demand forecasts in hard-to-reach areas, Roche holds additional inventory at different supply chain tiers and decoupling points.

Has a policy for reporting substandard and falsified (SF) medicines and vaccines in countries in scope. Roche has a policy for reporting SF medicines to relevant health authorities, but does not strictly specify the reporting timeframe. Roche, however, reports that it mostly occurs within 24h once a case is confirmed. It states that earlier reporting is possible with visual inspection, but does not specifically distinguish the reporting time frames of cases which only require visual inspection for confirmation.

Donates in response to an expressed need and monitors delivery to end user. Roche has a policy in place to ensure ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user; however, it is unclear whether this is defined as the patient. For example, it donated trimethoprim/sulfamethoxazole (Bactrim®) for a variety of bacterial infections to Mozambique in 2019 in response to cyclone Idai.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Roche is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible.