Roche falls seven places. It has advanced in compliance, with enforcement processes that also apply to third parties. It lags in R&D, as its commitments are not linked to need within the scope of the Index, it does not share intellectual property for R&D with relevant stakeholders and has no policy of basing R&D partnerships on pro-access terms. It applies equitable pricing strategies to only a limited portion of its products. In IP-management, Roche commits to not filing for or enforcing patents in low-income countries, and has enabled technology transfer for HIV/AIDS treatments. Roche donates products for diabetes and commits to building capacity in several areas.

In comparison with other companies, Roche’s public transparency, and therefore its commitment to accountability and knowledge-sharing, is generally low. For example, it does not publish: information about access commitments, performance measurements or outcomes; outcomes of stakeholder engagement activities or its stakeholder selection process; the results of clinical trials within a specified timeframe; whether it commits to registering all trials; its criteria for making registration decisions, or where products are filed for registration; whether it has issued drug recalls during the period of analysis; the status of its patents, or its position on the Doha Declaration.

**PERFORMANCE**

Roche can broaden its existing access commitments or partnerships. Supporting hepatitis C awareness raising in Vietnam for World Hepatitis Day in 2014, and in Indonesia in 2015. Signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

**TO BE NOTED**

Roche declined to provide data to the 2016 Access to Medicine Index, citing the fact that oncology – a major and expanding part of its business – is not in scope. The 2015 Index Methodology Report explains why, following a thorough multi-stakeholder consultation process, cancer medicines were not included within the scope of the 2016 Index. Roche’s performance in access to medicine has been evaluated since the first Index was published in 2008. Roche has important non-cancer products in its portfolio, including medicines for HIV/AIDS and hepatitis C, as well as diagnostics. Of these, 13 products are on the WHO Model Essential Medicines List (2015). Roche has both the capacity and the responsibility to improve access to these products. The Index also assesses companies’ overall approaches to access to medicine (not disease-specific), at the strategy-setting and governance levels. Based on these considerations, the 2016 Index evaluated Roche using data from past submissions and public sources.

**CHANGE SINCE 2014**

For Roche only, this section reflects performance changes that are publicly disclosed.

- In 2015, rolled out the Access Planning Framework, aiming to identify specific regional and national challenges, and developed more than 60 country-specific access plans.
- Has improved its compliance system as well as the transparency of its lobbying activities and enforcement processes.
- Has not been found in breach of anti-competition laws during the period of analysis.
- Still does not prioritise access in its R&D commitments or partnerships.
- Signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
- In 2014, extended its partnership with the Côte d’Ivoire Ministry of Health to facilitate access to hepatitis B, C and D treatments.
- Launched the Roche Pharma Africa Strategy in 2015, acknowledging the need for capacity building in sub-Saharan Africa in collaboration with local partners.

**OPPORTUNITIES**

Include other diseases areas in its access efforts. Roche can broaden its existing access initiatives (e.g., for cancer medicines) to improve access to medicine for other diseases, including for products on the WHO Model Essential Medicines List (EML). For example, Roche could build on its cancer-focused partnerships in countries such as Gabon, Indonesia and Kenya.

Ensure affordability for more products. Roche implements equitable pricing strategies for a small proportion of its portfolio. It can expand these strategies to more diagnostics and platform technologies, particularly its HCV diagnostic products, to ensure all relevant products are priced affordably where they are needed.

Agree access-oriented licensing terms for pipeline products. Roche has licensed danoprevir (now in phase II development) for supply in China. When licensing promising pipeline products for supply to emerging markets, Roche can ensure strong access plans are included in the terms and conditions of these partnership agreements (e.g., non-exclusivity, affordability).

Evaluate impact of capacity building efforts in sub-Saharan Africa. Through the Roche Pharma Africa Strategy, the company aims to increase access to medicines for viral hepatitis and women’s cancers. As it works toward this aim, Roche can help ensure effectiveness by evaluating the impact of its initiatives and publishing outcomes.
Roche is one of the world’s largest biopharmaceutical companies. It works in in-vitro diagnostics, tissue-based cancer diagnostics and diabetes management. It has two divisions: pharmaceuticals and diagnostics. Roche’s pharmaceutical business is focused on oncology, immunology, ophthalmology, infectious diseases and neuroscience. Roche Diagnostics offers a wide range of diagnostics and platform technologies, including molecular diagnostics, clinical chemistry and immunoassays, tissue diagnostics, point-of-care diagnostics and biotech solutions. These diagnostics cover a variety of diseases in scope, including metabolic, liver and heart diseases. As of 2014, it had sales in approximately 90 countries.

PORTFOLIO AND PIPELINE

Roche has a large portfolio of products for high-burden diseases, and a mid-sized pipeline of projects intended to address the needs of people in countries in scope: with 76 registered products and 14 R&D projects.

Roche has 19 medicines, 46 diagnostics and 11 platform technologies registered for diseases in scope. The majority target viral hepatitis, HIV/AIDS or ischaemic heart disease.

The company is developing products for five non-communicable diseases (NCDs) and four communicable diseases, with a heavy focus on viral hepatitis. Roche did not disclose products in discovery or pre-clinical stages of development.

A small proportion of its pipeline targets high-priority product gaps with low commercial incentive, including the hepatitis C medicine danoprevir. The Cobas 6800/8800 system was launched in Q4 2014 and approved for HIV/AIDS diagnosis by the FDA in Q4 2015. Roche committed to making its Cobas system available at lower prices in developing countries.

Roche is developing a beta-lactamase inhibitor and two medicines for viral hepatitis in partnership. Roche granted Ascletis rights to develop and manufacture danoprevir, in phase II for hepatitis C, in China.

Roche is developing products that target kidney diseases and hepatitis B. Both projects include trials in countries in scope, such as Brazil, Colombia and Mexico.

79% of Roche’s medicines are listed on the EML/or as first-line treatments: e.g., peginterferon alfa-2a (Pegasys®), ribavirin (Copegus®), alteplase (Activase®) and oseltamivir (Tamiflu®).

Approximately half of Roche’s portfolio is focused on communicable diseases.

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Roche Holding AG

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 19  SCORE 1.8

Biggest faller. Roche drops nine positions from 10th. Even though it has a clear access strategy, it drops due to low public transparency regarding progress toward access-related targets and stakeholder engagement.

Clear access strategy. Roche’s access strategy has a detailed set of objectives, namely: delivering innovation; improving affordability; strengthening healthcare infrastructure; increasing awareness; and supporting patients. It tailors its approach depending on local healthcare needs. In 2015, it rolled out the Access Planning Framework, aiming to identify specific regional and national challenges to providing access to medicine. It has also developed the Roche Pharma Africa Strategy, with a focus on 20 sub-Saharan countries, targeting viral hepatitis and some types of cancer.

Poor transparency on access-related outcomes. Roche publishes only general information about its access-related outcomes. It does not publish details, such as commitments, targets and performance measures.

Low transparency regarding stakeholder engagement. Roche publishes information related to stakeholder engagement, but does not publish the outcomes of these activities nor its stakeholder selection process.

Ad hoc engagement with local stakeholders. Roche engages with local stakeholders on an ad hoc basis. It publishes only general information, and provides no evidence that it incorporates the outcomes of these activities into its operations and strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 4  SCORE 2.6

Leading in market-influence transparency and compliance. Roche climbs from 12th to 4th. This is due to improvements in the structure of its compliance system and to its public transparency regarding lobbying activities and enforcement processes.

Mixed performance in ethical marketing. Roche has a code of conduct that includes ethical marketing provisions and that also applies to third parties. It makes no reference to incentives for sales agents, other than sales targets, nor does it disclose information regarding marketing activities or the payments it makes in countries within scope. The company has not signed the United Nations Global Compact.

Strong in transparency of lobbying practice. The company publishes its policy positions related to access to medicine, including biosimilars, anti-counterfeiting and clinical research. In its code of conduct, Roche describes its approach for managing conflicts of interest. This includes the description of cases where conflicts of interest may arise, and actions employees are expected to take. Nevertheless, it does not disclose information related to the political contributions it may make in countries within scope.

Found to have breached code of conduct. Roche was the subject of a settlement regarding a breach of a code of conduct during the period of analysis, involving the unethical marketing of a medicine in Australia.

Transparent enforcement process and disciplinary actions. In its 2015 Annual Report, Roche disclosed aggregate totals of internal investigations into alleged violations of its code of conduct, as well as of the sanctions and disciplinary actions taken in response.

RESEARCH & DEVELOPMENT

RANK 19  SCORE 1.4

R&D commitments not clearly linked to needs within the scope of the Index. Roche commits to R&D that addresses unmet product needs within the scope of the Index. Roche makes no commitment to meeting the specific needs of populations in countries in scope.

No policy for R&D collaborations. The company does not commit to ensuring access-oriented terms are included in its research partnerships.

Takes measures to ensure that clinical trials are conducted ethically. Roche has policies in place and takes measures to ensure its in-house and outsourced clinical trials are conducted ethically.

Does not fully publish trial results; has system for making patient-level data available. Roche does not specify a timeframe for publishing the results of its clinical trials. However, it does provide scientific researchers with access to patient-level data upon request, via clinicalstudydatarequest.com.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 20  SCORE 0.7

Biggest faller. Roche falls 9 places to 20th, mainly because it provides no information in several key areas, including price and volume-of-sales data, drug recall policy, registration targets and how it attempts to facilitate the rational use of its products.

Targets needs to a degree through equitable pricing. Public data shows that 5% of its relevant products have pricing strategies that target priority countries, reaching 70% of corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

No guidelines for sales agents. The company does not have pricing guidelines or a monitoring or auditing system for in-house or third-party sales agents.

No disease-specific registration targets. Roche does not report disease-specific registration targets. It does not publish its criteria for making registration decisions, nor does it reveal where its products are filed for registration.

No drug recall policy. Roche does not report having a drug recall policy. Roche does not pub-
lish whether it has issued drug recalls during the period of analysis.

Facilitating rational use of diabetes products in children. In 2014, Roche adapted the packaging of the glucometers and insulin pumps it donates via the Changing Diabetes in Children programme (run with Novo Nordisk). Its adaptations take account of language, literacy and demographic needs in ten relevant countries. In 2015, Roche supplied glucometers and testing strips to children in seven African countries.

PATENTS & LICENSING
RANK 11  SCORE 1.3

Commits to waiving patent rights in poor countries. Roche has publicly committed not to file for or enforce the existing patents it holds in Least Developed Countries and in low-income countries, and not to file for or enforce patents for ARVs in sub-Saharan Africa.

Public commitment to licensing for anti-retrovirals. Roche has publicly stated that it is open to the licensing of saquinavir (Invirase®), an alternative second-line HIV/AIDS treatment, should significant medical need be identified. Roche has previously completed technology transfers to 13 manufacturers for the supply of saquinavir to sub-Saharan Africa and to Least Developed Countries. It has granted licences for the production of oseltamivir (Tamiflu®) in order to support increased production.

Does not publish patent statuses. Roche does not publish any information about the status of its patents.

Does not take a public position on the Doha Declaration. Roche has not made a public statement about its position on the Doha Declaration, which commits to waiving patents over certain ARVs for public health use. The company did not disclose relevant activities (e.g., training partnerships or information-sharing with authorities) in countries in scope of the Index.

Limited disclosure about strengthening supply chains. Roche makes a general commitment to build manufacturing capacity in relevant countries. The company has 20 production sites globally, including in China, Brazil and Mexico, but did not disclose whether it undertook any manufacturing capacity building activities (e.g., in-house training, third-party technology transfers, or capacity building with unaffiliated partners) in the period of analysis.

Some activity in strengthening pharmacovigilance systems. Roche contributed to at least one workshop on pharmacovigilance in countries in scope during the period of analysis, specifically regarding biopharmaceutical medicines in Ghana. The company did not disclose examples of safety label updates for its medicines or pharmacovigilance-related information-sharing (e.g., voluntarily sharing post-marketing safety surveillance data with authorities) in countries in scope of the Index.

PRODUCT DONATIONS
RANK 12  SCORE 2.3

Among the fallers. Roche moves from 7th to 12th place. The company donates blood glucose meters (ACCU-CHEK®) in a structured donation programme for children with diabetes. Roche is involved in humanitarian aid donations, and has a clear public commitment to engaging in product donations.

Continues support for diabetes control. Roche has renewed its commitment to the Changing Diabetes in Children (CDIC) programme (which is coordinated with Novo Nordisk). In this programme, Roche provides strips and glucometers to measure blood sugar levels for all children involved.

Commits to social responsibility. Roche publicly commits to acting responsibly through philanthropic donations and non-commercial sponsorship. The company is transparent about its policy, which aligns with WHO guidelines.

Transparent about impact. Roche publishes information about several ad hoc donations, including the outcome and impact reports.

INVOLVED IN DONATIONS FOLLOWING NATURAL DISASTERS. Following natural disasters, Roche provides product donations to local partners. Following the earthquake in Nepal, the company donated more than 180,000 vials of ceftriaxone (Rocephin®), an antibiotic that treats a wide range of infectious diseases.

REFERENCES

Publicly available sources used to compile this report card include: Roche Finance Report 2015; Roche Annual Report 2015; Roche corporate website. Other references are available.