PERFORMANCE

Rises 1 place to 2\textsuperscript{nd} position. The company has launched a new approach to access, embodied by the Novartis Access Principles, which aims to expand access planning across the company’s pipeline.

Management: Holds 1\textsuperscript{st} place. Refreshed access strategy underpinned by the Novartis Access Principles, with CEO remuneration linked to access performance.

Compliance: Rises 13 places to 2\textsuperscript{nd}. Improved performance compared to peers in its internal controls and transparency, including financial support made to patient groups.

R&D: Rises to 3\textsuperscript{rd} place for its new approach to considering access planning for all new medicines.

Pricing: Holds 3\textsuperscript{rd} place, with an above-average performance across all pricing metrics but outperformed by leaders.

Patents: Falls 6 places to 16\textsuperscript{th}. Despite a greater level of transparency around its patents, it fails due to an incident regarding the IP around imatinib (Glivec\textsuperscript{®}) in Colombia.

Capacity: Falls 2 places to 3\textsuperscript{rd}, but holds strong against new metrics for good practice, notably in health system strengthening.

Donations: Rises two places to 3\textsuperscript{rd}, achieving a comparatively wide geographic coverage for its leprosy programmes which aim to eliminate the disease in 49 countries.

OPPORTUNITIES

Apply Novartis Access Principles to increase access across its entire late-stage pipeline. Novartis can work to ensure that its Access Principles are successfully applied to establish access plans for all new medicines in late-stage development regardless of disease scope. As the Novartis Access Principles were recently implemented in 2018, early success is critical to proving that access can be considered across the pipeline and successfully executed.

Expand equitable pricing strategies to cover all priority countries. Novartis’ nilotinib (Tasigna\textsuperscript{®}) for the treatment of cancer (leukaemia), is an on-patent product on the 2017 WHO Model List of Essential Medicines (WHO EML) and a first-line treatment. While equitable pricing strategies apply in some priority countries, the company could expand its scope to include all countries where need is the highest, including Egypt, Arab Rep., Kosovo, Kiribati, Micronesia, Fed. Sts., São Tomé and Principe and Tonga. Novartis has developed a new tool, Potential Affordability by Decile, to determine price segmentation in countries in scope. Novartis could apply this tool to address the affordability of products including valsartan (Diovan\textsuperscript{®}) for hypertensive heart disease and ischaemic heart disease in low- and middle-income countries.

Expand access to more manufacturers through voluntary licensing. Novartis can actively identify generic medicine manufacturing partners for the non-exclusive voluntary licensing of products for high-burden diseases. Possible products could include nilotinib (Tasigna\textsuperscript{®}) listed on the WHO EML for imatinib-resistant chronic myeloid leukaemia.

CHANGE SINCE 2016

- Established Novartis Access Principles to systematically integrate access strategies for all new products and Sandoz biosimilar launches beginning as early as Phase II.
- Reiterated its commitment to the control of non-communicable diseases with the Novartis Access Programme, expanding to new countries, such as Pakistan.
- Adapted the SMS for Life platform for stock management; the new, enhanced SMS for Life 2.0 has been launched in four countries since mid-2016.
- Launched the Better Hearts Better Cities initiative in May 2017 to improve cardiovascular health in low-income urban populations.
- Disclosed publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Published its expanded post-trial access policy to provide access to investigatory treatments for clinical trial participants that meet certain criteria after trials have concluded.
- Divests antibacterial and antiviral research.
PIPELINE for diseases and countries in scope

Comparatively large pipeline: 117 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 40, including three clinical candidates for the treatment of Plasmodium falciparum malaria.
Regulatory approvals: 6, erenumab (Aimovig™), a novel once-monthly self-injection for the prevention of migraines.
R&D focus: non-communicable diseases (cancer and COPD) and communicable diseases (malaria).
Access provisions: for 17 projects, most commonly registration and equitable pricing strategies.

Projects in the pipeline: 117

<table>
<thead>
<tr>
<th>Disease Area</th>
<th>Pre-clinical</th>
<th>Clinical I</th>
<th>Clinical II</th>
<th>Clinical III</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable*</td>
<td>18</td>
<td>12</td>
<td>6</td>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>Neglected tropical</td>
<td>1</td>
<td>12</td>
<td>6</td>
<td>0</td>
<td>22</td>
</tr>
<tr>
<td>Maternal and neonatal</td>
<td>9</td>
<td>12</td>
<td>10</td>
<td>6</td>
<td>37</td>
</tr>
<tr>
<td>Non-communicable</td>
<td>9</td>
<td>12</td>
<td>12</td>
<td>6</td>
<td>37</td>
</tr>
<tr>
<td>Multiple categories</td>
<td>12</td>
<td>12</td>
<td>10</td>
<td>6</td>
<td>40</td>
</tr>
</tbody>
</table>

Projects for R&D priority targets with access provisions: 14

Priority R&D**
Rest of pipeline

Statistics relate only to diseases and countries in scope.

PORTFOLIO for diseases and countries in scope

Largest portfolio: 127 products for diseases in scope (126 medicines; 1 contraceptive method).
Portfolio focus: non-communicable diseases (hypertensive heart disease and cancer) and communicable diseases (lower respiratory infections).
Essential medicines: 72% of Novartis’ medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 66% of Novartis’ medicines have first-line indications for diseases in scope.

Products on the market: 127

<table>
<thead>
<tr>
<th>Disease Area</th>
<th>WHO EML</th>
<th>Non-EML</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable*</td>
<td>75</td>
<td>17</td>
<td>92</td>
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<tr>
<td>Neglected tropical</td>
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<tr>
<td>Maternal and neonatal</td>
<td>26</td>
<td>17</td>
<td>43</td>
</tr>
<tr>
<td>Non-communicable</td>
<td>97</td>
<td>10</td>
<td>107</td>
</tr>
<tr>
<td>Multiple categories</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Novartis’ portfolio includes products such as clofazimine/dapsone/rifampicin (MDT-Combi) for the treatment of multibacillary leprosy and sacubitril/valsartan (Entresto®) for the treatment of ischaemic heart disease.

Essential medicines with first-line indications: 75

80% of Novartis’ medicines are listed on the WHO EML and/or as first-line treatments: e.g., the anticancer agents imatinib (Glivec®), anastrozole, tamoxifen and cisplatin.

BUSINESS CONTEXT

Three divisions: Innovative Medicines; Alcon; and Sandoz (generic medicines and biosimilars). Its Innovative Medicines division has two business units: Novartis Pharmaceuticals; and Novartis Oncology. Novartis Pharmaceuticals unit focuses on six therapeutic areas: ophthalmology; immunology; dermatology; neuroscience; respiratory; and cardiometabolic diseases. Novartis Oncology focuses on two therapeutic areas: cancers and rare diseases.

M&A news: 2018 sale of 36.5% stake in consumer healthcare joint venture to GSK; 2018 acquisition of cancer drugmaker Endocyte.

Sales in countries in scope

Statistics relate only to diseases and countries in scope.

Net sales by segment (2017) - USD

- Innovative Medicines: 33,025 MN
- Sandoz: 10,060 MN
- Alcon: 6,024 MN
- Total: 49,109 MN

Net sales by geographic region

- Europe: 2013: 15, 2014: 15, 2015: 15, 2016: 15, 2017: 15

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

**PERFORMANCE BY TECHNICAL AREA**

**GENERAL ACCESS TO MEDICINE MANAGEMENT**

**RANK 1 ** **SCORE 4.56**

Has a strong access-to-medicine strategy with board-level responsibility. Novartis 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 has three objectives focused on low-income markets: the control and elimination of disease; piloting new business approaches and engaging in R&D for unmet needs. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Novartis 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. Non-financial incentives include a global programme recognising associates making significant contributions towards corporate responsibility initiatives. Senior management achievement of access objectives is linked to compensation.

One of 16 companies working on impact measurement. Novartis measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments, objectives, targets and performance information. For example, for its Malaria Initiative, Novartis reports having provided more than 850 million treatments on a non-profit basis, to more than 60 countries since 2001, contributing to a significant reduction of malaria-related deaths. Furthermore, it is one of the companies that is measuring impact, with Boston University Metrics Framework, for at least one access initiative, e.g. Novartis Access.

Clear and transparent engagement approach that includes local stakeholders. Novartis 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 corporate responsibility materiality analysis, including research and surveys with internal and external stakeholders. Local stakeholder perspectives are incorporated into the development of its access strategies. It has some policies covering responsible interactions with stakeholders; namely on prioritising access to healthcare, innovation, patient health and safety, and ethical business practices.

**MARKET INFLUENCE & COMPLIANCE**

**RANK 2 ** **SCORE 3.14**

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Novartis has a code of conduct relating to ethical marketing and anti-corruption, and provides regular 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, Novartis newly rewards other aspects such as performance, innovation, collaboration, courage and integrity.

Internal control framework meets all Index criteria. Novartis has all the components looked for by the Index for an effective internal control framework to ensure compliance. Namely, it reports that it regularly conducts fraud-specific risk assessments. It has a global risk assessment, and a monitoring system to track compliance. It also has an auditing and review mechanism in place, which apply to third parties. Novartis demonstrates evidence of having procedures to segregate duties, so that decisions are checked by another party.

Above average transparency regarding access-related practices. Novartis publicly discloses its policy positions on access-related topics (e.g., its perspective on corporate responsibility including quality and safety of medicines, intellectual property, and its Access to Healthcare Perspective). The company discloses political contributions in countries in scope. It discloses its membership of relevant institutions and whether it provides financial support. Novartis discloses its policy for responsible engagement through its global policies for Responsible Lobbying and Anti-Bribery; its policies also include access perspective, intellectual property and quality and safety. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

**RESEARCH & DEVELOPMENT**

**RANK 3 ** **SCORE 3.55**

Publicly commits to R&D to meet public health needs. Novartis 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 public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Novartis has one of the largest pipelines in the Index with 117 projects. For diseases in scope where priorities exist, Novartis is active in 28 projects; 26 target priority R&D gaps.

Access provisions in place for 25% (9/36) of late-stage candidates. Novartis has a clear process in place to develop access plans during R&D through its Novartis Access Principles. This process considers all R&D projects for diseases in scope. In general, Novartis develops access plans for R&D projects in Phase II of clinical development. To date, Novartis has project-specific access provisions in place for nine of its late-stage R&D projects. Of these, four are being conducted in partnership.

Public policy to ensure post-trial access; commits to registering trialed products. Novartis 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, Novartis commits to registering it in all countries where clinical trials for the product have taken place.

**PRICING, MANUFACTURING & DISTRIBUTION**

**RANK 3 ** **SCORE 2.95**

Products: 127

Covered by EQ. Pricing Strategies which Target at Least One Priority Country: 72

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Novartis 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 implementing equitable pricing strategies for the majority of its products for diseases in scope.

Many new products in scope filed for registration in the majority of relevant priority countries. Novartis has filed 50% of its newest products for registration to date in more than half of
the 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.

57% of products have equitable pricing strategies targeting priority countries. Novartis’ overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 57% of its products for diseases in scope. These strategies apply to an average of 20% of priority countries. Almost all of these strategies apply inter- and intra-country pricing; these take into account an average of six and one socioeconomic factors, respectively. Novartis also applies equitable pricing strategies to three further products informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Novartis has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

**PATENTS & LICENSING**

Publicly discloses detailed information on patent statuses. Like most of its peers, Novartis 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. Novartis does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it does not provide evidence of good governance structures and process for mitigating conflicts of interest.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe.* Novartis has a policy of reporting cases of substandard or falsified medicines to relevant authorities and in some cases to WHO Rapid Alert. For example, Novartis reported a case of falsified artemether/lumefantrine (Coartem©) to WHO Rapid Alert in the period of analysis. However, it does not require reporting to occur within the timeframe of seven days looked for by the Index.*

**PRODUCT DONATIONS**

Responds to emergencies and humanitarian crises and tracks delivery. Novartis donated medicines on the request of relief agencies. For example, during the period of analysis, it donated medicines in response to Hurricane Harvey in Haiti in 2017. The company discloses that such ad hoc donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with the Swiss Red Cross and the International Committee of the Red Cross to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Novartis’ programmes are focused on neglected tropical diseases (NTDs) and non-communicable diseases. All three programmes are carried out in collaboration with partners such as WHO and the Max Foundation. Its programme for chronic myeloid leukemia supplies imatinib (Glivec®) and nilotinib (Tasigna®) in 57 countries and has been ongoing since 2002. Novartis reports that almost 71,000 patients have been reached in Index Countries during the period of analysis.

**BEST PRACTICES**

Leading approach to measuring impact
A developed, tested and applied methodology for measuring impact on society in financial, environmental and social (FES) terms.

Three companies incorporate framework of strict guidelines to reduce non-compliance
Astellas, GSK and Novartis stand out for their comprehensive internal control frameworks. Makes detailed commitment to providing post-trial access, goes further than peers
Detailed policy for providing investigational products to all clinical trial participants until the product is commercially available.

R&D unit dedicated to adaptive R&D aims to improve efficacy, safety and access
Unique R&D unit dedicated to adapting existing medicines to meet the specific needs of people living in low- and middle-income countries.

SMS for Life 2.0 expands to further prevent stock-outs of medicines
Enhanced mobile technology supply chain management system, now utilising new technologies and expanding to more countries and products.

Going beyond philanthropy: strengthening care at community level
Over 10 years, it has run initiatives alongside government health ministries and local NGOs to tailor healthcare activities to local needs.

**INNOVATIVE PRACTICES**

Novartis Access Principles to establish access provisions during development
A systematic approach to developing access strategies for each new medicine during development.

Novartis Access uses portfolio approach to address affordability for NCD products
Portfolio of 15 products for non-communicable diseases marketed to national governments, NGOs and other stakeholders, for 91 per treatment per month, supported by capacity building. ComHIP enables patients to access diagnosis and care at community level
Public-private partnership that embeds services for hypertension control and self-management in local communities