

Reviewer: Access to Medicine Foundation

Role of reviewer: Independent second party opinion.

Purpose: Novartis ESG Bond

Date of review: September 2020

Executive Summary:

The Access to Medicine Foundation is of the opinion that the KPIs chosen for this bond are relevant, robust and reliable for both public health and financial performance, and that the targets are realistic, but have challenges associated with them in the course of the next five years to achieve these targets.

The goal of the bond is aligned with the mission and principles of the Access to Medicine Foundationⁱ. The strategy to achieve the KPIs and the performance of the company to achieve these KPIs will have to be aligned over the upcoming years to the methodology of the Access to Medicine Indexⁱⁱ in order to demonstrate that the company significantly improves health outcomes of patients living globally, also in low- and lower middle-income countries and is performing in a sustainable, ethical and responsible manner to achieve these targets.

The key challenges in the next years to achieve these KPIs are the choice and management of the portfolio and initiatives which are influenced by internal governance and management and also influenced by external factors affecting patients reach and expansion of access initiatives.

Basis of the opinion and key considerations on the bond framework

1. Choice of portfolio for KPI-1 and initiatives for KPI-2:

The Bond stipulates that the 2025 Patient Access Targets will require Novartis to increase its Strategic Innovative Therapies Patient Reach by 200% or more (KPI-1) and to increase its Flagship Programs Patient Reach by 50% or more (KPI-2) by 2025, in each case compared to 2019. Novartis' ability to achieve these is based on increasing sales volume of Strategic Innovative Therapies and the reach of its Flagship Program therapies in low and middle income counties.

The level of ambition is realistic, based on the information shared to date. If the portfolio or initiatives change, the Access to Medicine Foundation would need to evaluate the growth trajectory (in the US and in emerging markets) for the chosen portfolio and the process employed to expand access in countries in more detail and compare the past growth and growth of similar products and initiatives by other companies.

The portfolio selected by Novartis for KPI-1 will be critical for success and define the value of such a bond in improving public health outcomes and building healthcare capacity in beneficiary countries. The portfolio selected for KPI-1 includes a number of products in the

Novartis portfolio. However, the volumes of patients are mostly based on a few selected key products. If and when one or more of these products lose exclusivity in the duration of this Bond, the speed of market entry of generics would be important to consider. If generic entry is fast, market share and success of reaching patient numbers with Novartis portfolio products will be compromised. However assuming that generic entry is fast, when in truth it is slower than expected may lead to a premature changing of portfolio, and Novartis should not leave markets that still need these key products and leave patients with gaps in treatments. Any shifts in portfolio selection should always align closely with the most critical need of patients, i.e. unique and vital products covering diseases with a highest global and regional burden, using the framework employed by the Access to Medicine Index would be useful in this regard. In principle, the company should consider addition of more newly launched products rather than terminating inclusion of products that lose exclusivity.

The choice of access initiatives under KPI-2 is equally important. Likewise, a significant portion of the baseline patient reach numbers are based on a limited number of key initiatives. These Flagship Program initiatives have all strong public and private partners, and have been evaluated over the years by the Access to Medicine Foundation to have met all good practice standards in the Access to Medicine Indexⁱⁱⁱ, and have also been running for several years, important for maintaining the integrity and enabling maximum patient benefit without any conflicts of interest. Any new initiatives should also maintain the level of good practice standards^{iv} expected externally. For these initiatives, Novartis collaborates with many implementing partners and distributors. As done internally for KPI-1, the company needs to identify and overcome challenges and opportunities for increasing access via the implementation partners for KPI-2.

2. Choice of countries:

To truly achieve the target increase for this bond under both KPI-1 and KPI-2, the choice of countries and populations within countries is critical. Coverage should include patients across the wealth pyramid, and spread also to countries with low income, high inequality and low human development (for example using the country classifications by the Access to Medicine Index^v which used the World Bank classification of income, human development as defined by UNDP and inequality in countries as defined by the UN Inequality-Adjusted Human Development Index.).

While the efforts of Novartis will include increasing patient numbers in markets where they already have a presence and reaching more patient groups, it is also important to enable access in countries that have not been reached yet. Improving patient access in these countries should include ensuring rapid and wide registration (prioritizing countries with a high burden of disease), ensuring affordable and quality health product access across the wealth pyramid, and enabling a sustained supply of products into low and middle income countries. All the efforts directed to achieve KPI-1 and KPI-2 should be aligned with international and national priorities. Further, it is important to consider where the company plans to increase its marketing and sales support to achieve the increase in patient numbers under KPI-1 and ensure that this is done in a responsible, ethical and cost effective manner.

3. External challenges:

The Covid19 pandemic and the strength of the health system to be able to benefit from these products and initiatives is important to manage. For example, Covid19 and other calamities have in some cases disrupted health access and supply and in other cases increased use of products.

4. Strategy outlined to achieve the targets.

The strategy (process) is still in development. A commitment to use the Access to Medicine Index frameworkⁱⁱ (especially for KPI-1 on Product Deployment, while conducting business responsibly on Governance of Access) would be important. The key principles that the company commits to follow to ensure early and broad access to products and ensure affordability and supply are aligned currently with the expectations of the Access to Medicine Foundation. However, Novartis will have to ensure that these principles are indeed followed and the performance of the company in the next years in achieving these targets will be monitored by the Access to Medicine Foundation's Access to Medicine Index, to ensure that patient reach is done in a sustainable and responsible manner across the whole company. The assumptions going forward need to be tailored to the situation the markets in scope of this bond are in, e.g. generic penetration after loss of exclusivity (speed and depth), compliance rate, launch plans for these markets, SKUs being used in the countries in scope, etc, and the status of the healthcare system and patient access situation.

About the Access to Medicine Foundation

The [Access to Medicine Foundation](https://accesstomedicinefoundation.org/) is an independent not-for-profit research organization based in the Netherlands. The Foundation has been for over 15 years evaluating the biggest pharmaceutical companies in the world on how they ensure access to medicine, especially in low and middle income countries and [incentivizing responsible business practices](#) to reach 2 billion people who lack access today. The Foundation is supported by the Bill and Melinda Gates Foundation, UK Foreign and Commonwealth Development Office and the Dutch Ministry of Foreign affairs and Ministry of Health. The Foundation works with governments, [over 100 investors](#), leaders in NGOs and academic and the pharmaceutical industry to shape policy and share best practices. The Foundation receives no financial or other support from the pharmaceutical industry and remains completely independent.

ⁱ <https://accesstomedicinefoundation.org/>

ⁱⁱ https://accesstomedicinefoundation.org/media/uploads/downloads/5f08703db73dc_Methodology_Report_for_2021_Access_to_Medicine_Index.pdf

ⁱⁱⁱ https://accesstomedicinefoundation.org/media/uploads/downloads/5bf3d93e33874_Access-to-Medicine-Index-Report-Card-Novartis-AG.pdf

^{iv} https://accesstomedicinefoundation.org/media/uploads/downloads/5f08703db73dc_Methodology_Report_for_2021_Access_to_Medicine_Index.pdf (page 45, table 5, Capacity building initiative flowchart)

^v https://accesstomedicinefoundation.org/media/uploads/downloads/5f08703db73dc_Methodology_Report_for_2021_Access_to_Medicine_Index.pdf (page 25 Geographic scope)