

Novartis Access 2016 one-year report

Capturing first learnings





About this report

With Novartis Access, we made a public commitment to transparency and dialogue. This report endeavors to do just that, describing first results, early learnings and challenges from our first twelve months on the ground. It also includes external perspectives and country updates, showcasing the progress we have made as we roll out the program. Further, the key performance indicators table at the end of the report lists our achievements against targets.

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Reflecting on one year of Novartis Access

First and foremost, I feel immense pride. Pride in the program; in the extraordinary partners we are working with; in what we have achieved in this short timeframe; and, of course, in my team, which is relentlessly working to get medicines in the hands of chronic patients.

We have so far signed memoranda of understanding in Kenya, Ethiopia and Rwanda. The rollout is progressing well in Kenya, with the fifth medicine delivery on its way – serving as a “proof-of-concept” for future rollouts. In addition, we are in discussions with governments to introduce the program in more than 10 countries on three continents. We are also collaborating with the International Committee of the Red Cross to provide treatments for refugees in Lebanon. Submissions are ongoing, with 370 submissions already completed in 21 countries.

We have started work to measure the impact of Novartis Access in Kenya, and this methodology could help other companies evaluate their own access programs.

Since its launch, Novartis Access has generated considerable interest, serving as a platform to foster a public debate on how to scale up care against chronic conditions in lower-income countries – as well as on the role of the private sector. Yet it will take an even larger community of advocates, from NGOs, policymakers and ministries of health through to national procurement agencies, to bring forward holistic solutions to curb chronic diseases.

Although there is much to celebrate one year into the program, we must also reflect on learnings and overcome challenges.

We underestimated the paradigm shift our portfolio approach would require in countries’ procurement systems and regulations. Novartis Access is an operational innovation that could support countries in their effort to offer universal health coverage; yet frameworks need to be in place, such as up-to-date essential medicines lists and treatment guidelines, for such a program to succeed.



We also have to counter skepticism from external stakeholders about the long-term nature of our commitment; and from internal colleagues regarding the potential risk of negatively impacting our core business in developing countries. I believe we are now starting to overcome these challenges as people understand Novartis Access has been designed to become a scalable social business over time.

We are still at the very early stages of our journey. We don’t pretend to have *the* solution to improving access to medicines, but we believe Novartis Access and programs like it offer compelling examples of how the pharmaceutical industry can work with others to overcome access issues in poor countries.

My team and I very much welcome your feedback: novartisaccess@novartis.com

Harald Nusser
Head Novartis Social Business

Novartis Access at a glance

Novartis Access offers a portfolio of 15 on- and off-patent medicines addressing key noncommunicable diseases (NCDs): cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer.

The portfolio is offered as a basket to governments, NGOs and other public-sector customers at a price of USD 1 per treatment per month. Depending on public subsidy levels, patients may either receive Novartis Access medicines free of charge or purchase them at a low price to manage their chronic condition long-term. For those who need to purchase their treatments, we are working with our partners to minimize markups.

Various treatment options are offered for each disease, including well-proven and standard first-line treatments, as well as some of the latest treatment

choices. The treatments in the portfolio offer the same quality and supply security as medicines sold in developed countries. In addition, they have all been qualified for use in tropical climates.

Beyond the portfolio, Novartis Access offers capacity building activities to support healthcare systems in preventing, diagnosing and treating NCDs.

We are striving to roll out the program in 30 countries in the coming years – depending on governmental and stakeholder demand – aiming to reach 20 million patients by 2020.

2016 highlights

USD 1

Price of one treatment per month in the Novartis Access portfolio

15

Sandoz and Novartis Pharma products

75%

Of NCD deaths occur in low- and middle-income countries

Top 7

Causes of deaths in low- and middle-income countries addressed by Novartis Access

370

Product submissions in 21 countries

124 433

Monthly treatments delivered

20m

Patients reached by 2020

90+

Healthcare facilities to be trained on NCD management in Kenya

“A key learning from HIV programs was that you cannot build awareness until there is treatment. It’s the same with NCDs. It’s access to treatment that gets individuals and families to learn about heart disease and diabetes and to come forward for diagnosis.”

Dr. Samuel Mwenda, General Secretary (Ex-Officio),
Christian Health Association of Kenya



“Chronic diseases are not rich-country diseases, nor old-people diseases. Eight million children, adolescents and working-age adults die each year in lower-income countries from these diseases. That’s more than AIDS, TB and malaria combined.”

Dr. Jonathan D. Quick, President and CEO, Management Sciences for Health (MSH)



Interview with Professor Vikas Tibrewala

Professor Vikas Tibrewala, former Faculty Member at INSEAD, is writing a case study on Novartis Access to be published in 2017. As part of his research, he interviewed senior executives at Novartis and external stakeholders, including several in Kenya, the first country to implement the program. He shares key insights from his discussions.

1. Offering a portfolio of drugs against NCDs at USD 1 per treatment per month is unprecedented in the industry. Do you see any risks associated with this approach?

Offering very affordable pricing in a portfolio model is a transformative idea and, as such, carries great opportunities but also risks. When Novartis Access was launched, the expectation was that customers (governments, NGOs or other public-sector buyers) would buy all 15 medicines. Yet, one year into the program's rollout in a few countries, the company is realizing this may need to change for two main reasons. First, procurement agencies or sometimes even regulations in countries where Novartis Access is rolled out (or planned for rollout) typically source single drugs, molecule by molecule, and are not geared to opening multi-product tenders. Second, the portfolio model requires considering the average pricing for the entire package of drugs as opposed to the prices of individual drugs. In some cases, older generics may be available for less than USD 1. While these cheaper drugs may not always be at the Novartis quality standards, they are nonetheless attractive for many customers.

When taking into account the entire portfolio, this model is far more cost-efficient than purchasing the 15 drugs individually, especially for the more advanced drugs. Yet clearly, because it is breaking new ground, the portfolio model requires a paradigm shift in how countries procure medicines. It will take time, and Novartis may need to be flexible with its portfolio approach to better suit market realities.

2. Did the stakeholders you meet express worries?

I spoke to several stakeholders, including procurement agencies, government officials and NGOs in Kenya, and they were generally very supportive and positive about Novartis Access. Yet, some did ask: "What would happen if Novartis walked away?" I think the company needs to repeat again and again that they are in for the long haul. Novartis needs to reassure patients and people in the countries and tell them: "Once you have the drug, you're safe, we won't go away." Doing nothing is bad but doing something good and then stopping is even worse.

3. Novartis Access provides much needed affordable drugs. But what more is needed to improve access to healthcare?

Novartis made the great commitment to bring affordable drugs against NCDs to people in poor countries – but affordability of drugs is just the tip of the iceberg. The underlying question is: how can we help ensure healthcare systems in the countries commit to make the Novartis commitment sustainable?

When looking at ways to improve access to healthcare in these countries, we need to look at the ecosystem of care holistically, and consider the other crucial elements that make healthcare systems function, notably the capacity to detect, diagnose and treat chronic patients, and develop efficient distribution channels.



NCDs require early detection and long-term care, and this is a challenge even in the most economically developed markets. As you can imagine, in the majority of the program's target countries, this capacity is very limited. For example, Ethiopia, a country of almost 100 million people, has just eight oncologists. And they are all based in the capital of Addis Ababa! This means the chances of people in rural communities getting checked and diagnosed are extremely limited.

“The underlying question is how can we help ensure healthcare systems in the countries commit to make the Novartis commitment sustainable?”

Very often chronic patients have no visible symptoms, unlike acute infectious diseases like malaria, so they feel no urgency to see a doctor. When they do, the clinic may be a day's walk away, and the poorest of the poor simply cannot afford to take a day off. If they do get to the clinic, will the healthcare provider have the capacity to make the right diagnosis and offer appropriate treatment?

This is why we really need to define how to best unlock the other blockages, beyond affordability of drugs. My view is that Novartis can be an enabler, but ultimately, responsibility lies with healthcare systems in the countries. Without their leadership, society will not be able to reap the full benefits of the program.

4. Can Novartis “walk the talk” of its ambition?

If Novartis Access delivers on its ambition, meaning if the program expands access to affordable drugs and improves education and awareness about NCDs, the challenge will be to deliver potentially enormous volumes of drugs. Success will be measured in terms of the number of patients reached as well as in the capacity of Novartis to meet the demand. The risk here is that the volume of drugs needed would strain the manufacturing capacity of Novartis, or any other company for that matter. Needless to say this “nightmare of success” could lead to a massive trust issue. But I am confident that Novartis can meet the challenge; they have been able to ramp up their antimalarial production capacity 25 times in just two years.

5. How can we ensure integrity and efficiency in the distribution channels?

Typically, the distribution channels in the countries Novartis Access is targeting are fragile and highly fragmented, with the private sector playing a key role. Diversion and leakage of medicines from public channels into these private channels is a real risk, and would be detrimental to the program and to patients themselves. Beyond supply chain efficiency and integrity, another crucial question is markups. In such a highly fragmented distribution system, this would also negatively impact access and affordability. Clearly, these are not issues that Novartis can address alone. While the company is working with several partners on the ground with expertise in pharmaceutical supply chains to find the best solution, more partnerships are needed.

How it all started

In December 2014, our CEO Joseph Jimenez mandated the Novartis Access to Medicine Committee to develop options on how our company could provide lower-income countries with affordable medicines against noncommunicable diseases (NCDs).

Given the long-term nature of chronic conditions, he urged the committee to develop a model that was scalable and could become a sustainable business over time – providing patients with affordable medicines while generating a small profit for Novartis. He posed an additional challenge: instead of focusing on one chronic condition and one drug, could we tackle the NCDs that cause the largest number of premature deaths?

Over the next months, in discussion with stakeholders from academia, global health institutions, governments and the private sector, the committee determined the therapeutic areas and countries in scope. We used the list of the 107 countries included in the Access to Medicine Index as the basis. Of those, we identified 30 countries in Africa, Asia, Latin America and the Commonwealth of Independent States (CIS) where our program would have the greatest health outcomes: those with high unmet need in terms of NCD treatment; with a strong Novartis presence; and with existing healthcare infrastructure and/or sufficient NGO presence to make a launch feasible and the program sustainable.

We identified four key NCD areas (cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer) where even WHO-designated essential

medicines were not readily available and affordable in these 30 countries. In total, we chose to include 15 on- and off-patent treatments in the portfolio.

Yet, we knew that launching a portfolio of medicines was not enough. In order to ensure maximum impact, we needed to raise awareness and strengthen healthcare systems and capabilities, including training on diagnosis and treatment. Partnerships with governments and local and international organizations would be essential to the success of the program.

After finalizing the portfolio and the rollout countries, we needed to determine what would be an affordable price. It took much debate and calculations to set the average price at USD 1 per treatment per month for the basket. Although we had no firm projections on the uptake of the program, we decided to take a calculated risk based on the anticipated volume opportunity the program could generate. In the end, three elements were critical in the price decision: the anticipated scale of the program, the portfolio structure, and the significant generic component of the offering.

Novartis Access was endorsed by the Board of Directors and the Executive Committee of Novartis in August 2015 and was launched in September 2015.

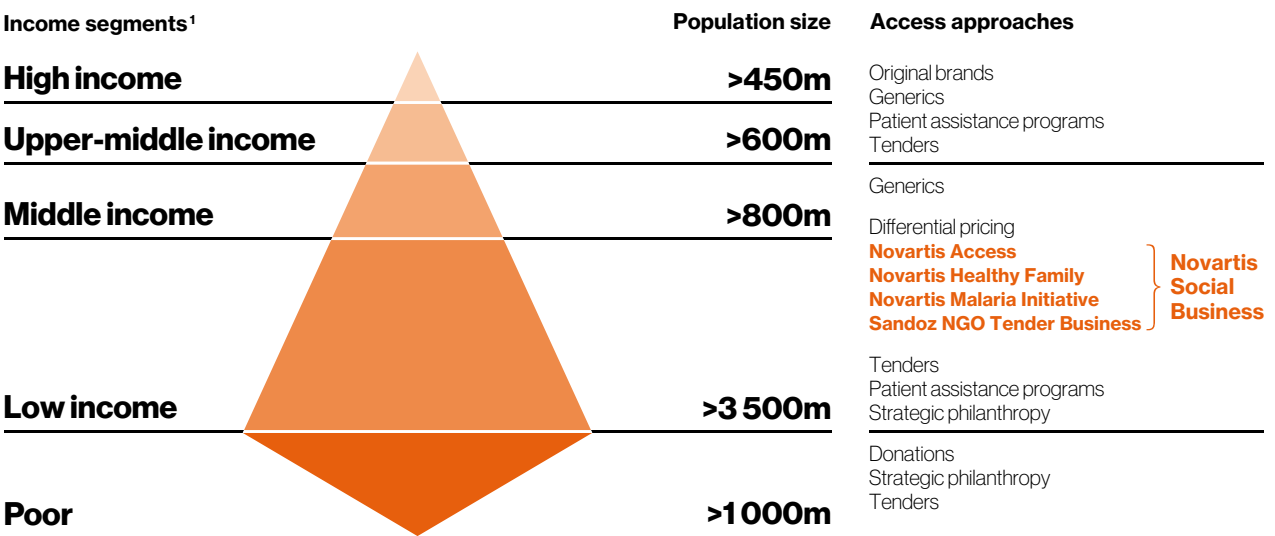
“There’s simply no way for governments and social groups alone to develop and execute all of the interventions needed to prevent and treat diseases. A collaborative effort is needed to address the underlying causes of poor health, leveraging the expertise and resources of companies. This kind of prominent role for the private sector isn’t just desirable, it’s essential.”

Joseph Jimenez, Chief Executive Officer, Novartis



Novartis Access fits into our company’s strategic framework, which includes a range of approaches to enhance access to healthcare for patients at every level of the economic pyramid.

Novartis Access strategy: Reaching more patients



¹ PEW Research Center with data from World Bank PovcalNet (data 2011)

Lower-income countries facing a double disease burden

Noncommunicable diseases (NCDs), also known as chronic diseases, are growing in low- and middle-income countries (LMICs).

Annually, 28 million people die from chronic diseases in these countries, representing nearly 75% of deaths from NCDs globally. Together, cardiovascular diseases, diabetes, respiratory diseases and cancers are responsible for 82% of all NCD deaths globally. Yet, less than 2% of all donor funding is allocated to chronic diseases.¹

Beyond the human suffering chronic conditions cause, projections indicate they will cost society USD 47 trillion over the next two decades² – with USD 21 trillion of this loss occurring in LMICs – due to reduced workforce productivity, curbed economic growth and reinforced poverty.

Managing chronic diseases is particularly difficult in LMICs, as these countries are still weighed down by infectious diseases such as HIV/AIDS or malaria, and are now increasingly faced with a double disease burden. In many ways, this new challenge is a result of past successes such as urbanization, industrialization and improvement in life expectancy. The health systems which were established to deal with acute infectious diseases have not caught up with the new situation for NCDs.

Preventing and controlling NCDs

Chronic diseases require early detection and, often, life-long treatment. Yet, healthcare systems in LMICs are ill-equipped to provide these as they suffer from an under-investment in healthcare infrastructure, which leads to a lack of clinics and hospitals, shortages of medical staff, poor medicine distribution networks and low numbers of trained healthcare providers.

An important way to curtail NCDs is to focus on lessening the risk factors associated with these diseases. Low-cost solutions exist to reduce the most common modifiable risk factors, mainly tobacco and alcohol use, unhealthy diets and lack of physical activity. This is why it is essential to create awareness about the risks in the first place.

But the greatest impact can be achieved by creating healthy public policies that promote NCD prevention and control, and reorienting health systems to address the needs of people at risk of such diseases.³

While we can build on the learnings from infectious diseases, we also need new solutions that are not dependent on donor funding, such as scalable business models, to help guarantee a sustainable supply of affordable medicines over time.

“We have to break the myth that NCDs are diseases of old age and affluence. NCDs usually affect people in the prime of age, between 35 and 60, people who work and are breadwinners. These are the people who move the economy. [...] NCDs push families deeper and deeper into poverty. We need to look at NCDs as a developmental issue.”

Dr. Joseph Kibachio, Head of NCD Division,
Kenyan Ministry of Health

¹ Lim SS, Vos T, Flaxman AD, Danaei G, Shibuya K, Adair-Rohani H et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*, 2012; 380(9859):2224-2260.

² World Health Organization and WEF, From Burden to “Best Buys”: Reducing the Economic Impact of Non-Communicable Disease in Low-and Middle-Income, 2011, [p.3]. Available at: http://www3.wefo-rum.org/docs/WEF_WHO_HE_ReducingNonCommunicableDiseases_2011.pdf. Last Accessed May 2015.

³ WHO, Noncommunicable diseases fact sheet, January 2015: <http://www.who.int/mediacentre/factsheets/fs355/en/>

Co-creating solutions with our partners on the ground

Affordable medicines alone are not enough. Expanding access to healthcare and medicines is often jeopardized by multiple challenges, such as shortages of trained healthcare professionals, poor disease understanding, lack of healthcare infrastructure in rural areas and unreliable distribution networks for medical supplies.

This is why we are partnering with organizations that can help strengthen every part of the continuum of care. This may also require companies which normally compete to work together for the public good.

We have identified priority needs in three areas:

1. **Capacity building** to train medical professionals and healthcare workers on screening, diagnosis and treatment, and to raise awareness and educate local communities about NCDs
2. **Distribution chain integrity** to ensure products are delivered through designated channels, re-fills are available in rural areas with sufficient shelf life and no excessive markups are charged to patients
3. **Measurement and evaluation** to assess disease awareness, prevalence, treatment availability and price at both facility and household level



Type of partner / Objective of partnership

Novartis Access partners

Nongovernmental organizations and faith-based organizations

- Increase knowledge or develop physical capacity and capabilities in public healthcare systems and institutions (scaling up of diagnostics tools, disease awareness programs, healthcare provider training, NCD guidelines, etc.)
- Christian Health Association of Kenya (CHAK)
- International Committee of the Red Cross (ICRC)
- Kenya Conference of Catholic Bishops (KCCB)
- Kenya Red Cross Society (KRCS)
- Mission for Essential Drugs and Supplies (MEDS)

Academia and research

- Provide necessary transparency in challenging environments
- Evidence impact to guide future investment and implementation of access programs
- Boston University (BU)
- Management Sciences for Health (MSH)

One year into the program: country updates

Kenya

Kenya was the first country to implement Novartis Access in October 2015.

While the country has made great strides in controlling AIDS and other infectious diseases, chronic diseases such as diabetes, heart disease and cancer are on the rise.

Today, NCDs account for 27% of deaths in Kenya and are expected to contribute to more than 60% of the total national mortality by 2030. Overall, NCDs cause more than 50% of inpatient admissions and 40% of hospital deaths, dominating healthcare budgets in Kenya.

In 2015, the Kenyan government launched a National NCD Strategic Plan 2015-2020 outlining 10 objectives to prevent and control NCDs.

In Kenya, on average, people earn USD 100 per month and almost half of the population lives below the poverty line. Most Kenyans with modest incomes have to pay for treatment themselves, as the National Hospital Insurance Fund only applies to 15% of the population. Expensive medicines are thus often an obstacle to the long-term care of chronic diseases.

Capacity building activities

We have joined forces with the Christian Health Association of Kenya (CHAK), the Kenyan Conference of Catholic Bishops (KCCB) and the Kenyan Red Cross Society (KRCS) to build capacity to diagnose and manage chronic diseases in local facilities across the country. This includes plans to reach one million people with education campaigns on diabetes in the next two years. Other activities will include campaigns to screen and diagnose people for diabetes and hypertension both in health facilities and local communities, as well as training for healthcare workers.

As part of the collaboration with Novartis, KRCS will also focus on the thousands of refugees living in the Kakuma and Dadaab camps, which are now confronted with significant cases of diabetes, hypertension, cancer and asthma.

In 2016, 13 regional meetings brought together healthcare personnel from public and faith-based health facilities to raise awareness about the availability of Novartis Access medicines in Kenya. Further, under the helm of the NCD unit of the Kenyan Ministry of Health, four “train the trainer” workshops will be held in the next months with representatives from CHAK, KCCB and the KRCS, each covering a specific NCD area. Participants will also receive training based on the national Kenyan NCD guidelines. Following these workshops, participants will train workers at their own affiliated facilities, i.e. 50 CHAK facilities, 40 KCCB facilities, and 2 KRCS facilities.

“For decades, the health system in Kenya has focused mainly on infectious diseases, and as a result the infrastructure to treat chronic conditions is weak. Chronic diseases are now also taking an increasingly heavy toll on refugee populations. In Kenya, in the Dadaab camp alone, in just one year there were about 27 000 medical consultations for NCDs, of which 43% for cardiovascular disease alone.”

Dr. Abbas Gullet, Secretary General, Kenya Red Cross Society

Distribution and supply chain integrity

We are working with the Christian not-for-profit organization Mission for Essential Drugs and Supplies (MEDS) to distribute Novartis Access medicines to faith-based facilities in Kenya. The first treatments reached rural facilities in three counties in February 2016 with patients paying approximately USD 1.50 per treatment per month. The 50 cents price difference is due to importation, clearance, warehousing, and distribution markups covering the costs in the distribution chain. We work with our distribution partners to minimize markups on Novartis Access products and ensure this is secured contractually. In Kenya, as responsibility for healthcare is decentralized and counties have different pricing policies, prices paid by patients may also vary from county to county depending on subsidy levels.

In 2016, 10 out of the 15 Novartis Access medicines were approved in Kenya. Five shipments totaling more than 57 000 monthly treatments were delivered to MEDS – of which more than 16 000 reached 50 faith-based facilities and 6 county governments. Orders have been placed for 100 000 monthly treatments. We expect to roll out the program to all 47 Kenyan counties by the end of 2017.

In order to ensure treatments reach the right patients at an affordable price, we are working with Management Sciences for Health (MSH) to assess the supply chains in public and faith-based healthcare facilities in Kenya and identify any risks that may be detrimental to product integrity. Emphasis is on tracking and monitoring stock, product leakage and shelf life expiry.



The story of Peninah

Peninah's children convinced her to go to the clinic. They argued that a racing heartbeat and headaches were not normal signs of old age. The 65-year-old Kenyan farmer was reluctant at first, but after taking that first step, she is now going for regular checkups at the health clinic in Mwea and taking medicine to help keep her blood pressure in check.

The visit to the doctor and the blood test cost Peninah 300 Kenyan Shillings (about USD 3) every month, not including the treatment. Peninah is one of the first patients to benefit from Novartis Access.

Improved access to treatment will shift attitudes among Kenyans who are increasingly affected by chronic diseases. For instance, on a typical day, the clinic in Mwea where Peninah receives treatment has more than 300 people waiting for visits, checkups and prescriptions, the vast majority related to chronic conditions.

Peninah has decided to share her patient experience with her community. She now chairs the local women's group in Kiangegwa village, which meets monthly and discusses healthcare topics, from basic sanitation to disease prevention and management.

Findings from the Management Sciences for Health (MSH) assessment in Kenya

Global health nonprofit MSH has a track record of building locally-led and locally-run health systems and has been a longtime partner to the Ministry of Health in Kenya. In 2016, MSH completed supply chain assessments in 22 public and private faith-based health facilities which distribute Novartis Access medicines in Nairobi and Kirinyaga counties. While all facilities had basic equipment to measure blood pressure and blood glucose levels, this was not matched by availability of essential diagnostic and monitoring tests and equipment for all NCDs.

Findings revealed that health facility storage infrastructure and conditions (e.g. insufficient space and inadequate temperature control), management information systems (e.g. paper-based and poor record keeping) and inventory management practices (e.g. non-systematic inventory counts, informal expiry management) represented the highest risks for product integrity.

A feedback workshop was hosted by the Ministry of Health at the end of 2016 with representatives from county health services, public and faith-based health facilities, NGOs and supply agencies to discuss results and jointly agree on corrective actions.

Ethiopia

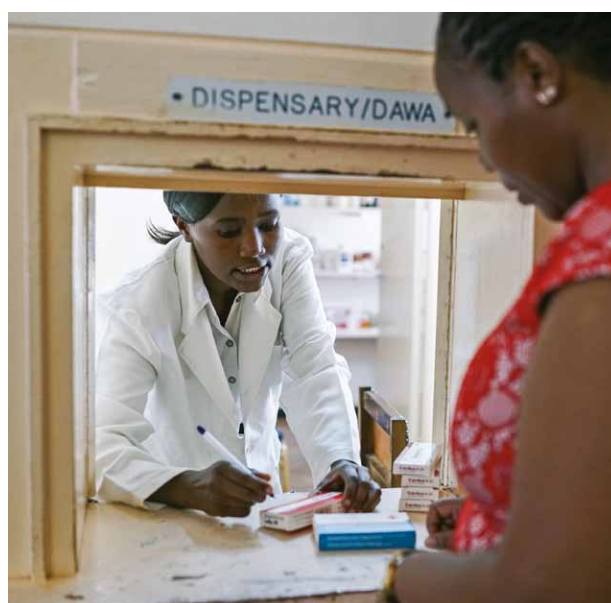
NCDs account for 30% of deaths in Ethiopia. Along with Kenya, Ethiopia was among the first countries to sign a memorandum of understanding for Novartis Access in late 2015. A first shipment of 30 000 Novartis Access treatments against high blood pressure was coordinated through the Ethiopian Red Cross in 2015.

The national health system in Ethiopia is highly centralized and all medicines are procured as single molecules through the national procurement agency (Pharmaceuticals Fund and Supply Agency, PFSA). Negotiations are still ongoing to put in place a call for tenders for an access program, which would include NCD medicines and capacity building activities.

Rwanda

Rwanda has created a comprehensive health insurance system (covering 91% of the population, with the poorest paying nothing) together with a network of 45 000 community health workers.

Success against infectious diseases has increased average life expectancy from 39 years in 2004 to 59 years in 2014, leading to a rise in NCDs. The WHO estimates that NCDs are now responsible for 36% of all deaths in Rwanda.



Following the launch in 2015 of a national strategy to increase investment in prevention, diagnosis and treatment of NCDs, the Rwandan Ministry of Health signed a memorandum of understanding for the implementation of Novartis Access in September 2016. We expect the first product delivery in the next months.

“This collaboration [...] will hopefully allow us to include more patients in our NCD program. If people are aware that treatment is available and affordable (actually for free for the patients for the time being), we hope that they will be sensitized to attend screening in one of the ICRC-supported primary care centers.”

Rodolfo Rossi, former Health Coordinator for the ICRC in Lebanon

Vietnam

The WHO estimates that NCDs account for 74% of deaths in Vietnam. Currently, the country allocates 7% of its GDP to healthcare, almost twice as much as India. Novartis has signed a broad memorandum of understanding with the government, which also covers NCD interventions such as Novartis Access.

It should take approximately two years for the Novartis Access portfolio to be registered in Vietnam. As foreign companies are legally required to work through a domestic wholesaler to distribute pharmaceuticals, we are currently in discussions with our distributors to ensure product markups are kept to a minimum. We will likely introduce the first Novartis Access products via our existing “Healthy Family” program in selected provinces in early 2017.

Caring for refugees in Lebanon

For decades, the International Committee of the Red Cross (ICRC) has treated people with war wounds. Yet, today, diabetes can cause more amputations than war wounds in certain contexts.

In March 2016, the ICRC and Novartis Access launched a pilot to improve access to treatment for Syrian refugees in Lebanon, as well as underserved Lebanese and Palestinian patients, suffering from type 2 diabetes and high blood pressure. Together, these two diseases account for more than 50% of deaths in Lebanon.

The country is experiencing the largest influx of refugees in recent history, with refugees accounting for about one third of the country’s total population, over-stretching the already fragile healthcare system. Moreover, Lebanon reports that around 30% of its adult population is obese or has elevated blood pressure.

In total, in 2016, more than 26 000 monthly treatments of Novartis Access medicines were delivered to Lebanon.

Other countries

We are in discussion with governments and local stakeholders in more than 10 priority countries in sub-Saharan Africa, Southeast Asia, Central America and Central and Eastern Europe who have shown interest in the program.

Product submissions and registrations

Before each country launch, medicines need to be approved by regulatory authorities. This process usually takes between six months and two years. Until now, 370 submissions were filed in 21 countries across Africa, Asia, the Commonwealth of Independent States and Latin America.

Our experience to date shows that country authorities are interested in the portfolio and the program, as demonstrated by several fast-track approvals. In Kenya, approvals were gained in two months, while Rwanda approved the entire portfolio in just three weeks. In Ghana, where the typical approval time is nine to twelve months, four products also received marketing authorizations in three weeks.

Learnings and challenges

One year into the program, there are many learnings to build on.

Portfolio presents challenges but they can be overcome

The portfolio model has emerged as the biggest obstacle to swift public sector uptake. Moving from single drug procurement to a portfolio approach requires a mindset shift and a change in procurement systems – and this takes time.

As different countries have different healthcare needs, we understand that we have to adapt our portfolio offering to meet local requirements. While it is important for Novartis to maintain a commercial balance between cost and value through a certain (sub-)basket of products, there is still enough flexibility to maintain the USD 1 price per treatment per month for a subset of the portfolio.

Over the past year, we have engaged governments in the portfolio discussion in several ways – from exploring options for a government to issue a tender for a portfolio of NCD medicines and capacity building; to piloting Novartis Access on a small scale to demonstrate public health benefits; to assessing private sector approaches.

Moving from collaboration to co-creation

Early on, we identified three areas where partners would be instrumental: capacity building, distribution chain integrity, and measurement and evaluation. Although needs were clearly formulated, we knew we would have to allow for trial and error. This required adapting our business mindset to acknowledge that we did not have all the answers and needed to take a learning-by-doing approach with our partners. It also required a fundamental shift toward partnerships based on true co-creation, where partners share strengths and weaknesses. Lastly, we may also need to go beyond the public-private partnership model with one company only and consider broader private-sector collaborations, including with other manufacturers.

Supply chain integrity is key to ensuring affordable long-term access

The drug distribution system in most lower-income countries is complex, with many intermediaries

between the manufacturer and the patient. Medicines bought by countries at low prices sometimes end up with a 300-400% or even higher markup, leading to unaffordable prices in healthcare facilities. Further, stockouts of medicines are frequent as these countries often have weak distribution networks.

We are working with partners such as Management Sciences for Health and Boston University to help ensure we can deliver a reliable supply of high-quality medicines at affordable prices. We are also exploring the potential to adapt the SMS for Life model used to prevent stockouts of antimalarial medicines in sub-Saharan African countries to healthcare facilities distributing NCD treatments.

National essential medicines lists should drive our efforts

Thirteen of the fifteen medicines included in the Novartis Access portfolio are either on the WHO Model List of Essential Medicines or pertain to a class included in the list. Drawing from the WHO list, countries have established their own national essential medicines lists which set the policy for medicines procurement and use in the public and private sector. Yet, national essential medicines lists often comprise fewer products than the WHO list (in Kenya for instance, only 8 of the 15 Novartis Access medicines are listed on the country's list) and differ from one country to another, with some lists being limited and even outdated. This makes it nearly impossible for procurement agencies to order the Novartis Access portfolio. Up-to-date country lists and treatment guidelines are thus critical to ensure patients have access to the latest cost-effective therapeutic options.

While we initially thought that including patented medicines in our portfolio – even if these medicines were not on the WHO Essential Medicines List – would demonstrate our desire to offer treatment standards found in the US or Western Europe to lower-income countries, we later understood that national essential medicines lists and treatment guidelines should drive our efforts as solutions need to be home-grown. It was not until September 2016 that the first on-patent treatment was ordered.

“Novartis Access is a natural extension of two important contributions our company makes to society: developing innovative medicines that help people fight disease and working to get them to as many people as possible. We know we will need to keep an open mindset and learn as we progress on this journey.”

Joerg Reinhardt, Chairman of the Board of Directors, Novartis

Shifting from an acute to a chronic care model

Many lower-income countries are facing a double disease burden of infectious and chronic diseases. While they are still devoting considerable resources to fighting acute diseases like malaria or HIV/AIDS, they must now also turn their attention to NCDs. Shifting from an acute to a chronic care model is a challenge for most healthcare systems in lower-income countries as they are not geared toward providing the long-term care that chronic conditions require. Typically, people with chronic conditions rely more heavily and for a longer time on the healthcare system, and consume more resources. It is only by strengthening healthcare system capabilities in NCDs, in terms of disease awareness, diagnosis and treatment, that countries will be able to cope with this dual challenge.

Yet, there is much to learn from infectious diseases, and countries should leverage these learnings to improve NCD care. For instance, a key insight from the HIV/AIDS epidemic is that a diagnosis is of no help if there is no medicine available and affordable to treat the condition.

New financing mechanisms required

Of all major global health areas, NCDs receive the smallest amount of donor funding, accounting for less than 2% of all donor assistance for health.^{1,2} This is partly due to development aid policies, which have until recently focused on the health priorities outlined by the Millennium Development Goals that excluded chronic diseases, as well as the misperception that NCDs are diseases of affluence or old age. While low-income countries can access funding for treatment for infectious diseases through the Global Fund, no such financing facility exists for NCDs.

New financing mechanisms are thus needed to help countries establish basic primary care, which is the bedrock for effective management of NCDs. This is likely to come from a combination of increased funding from governments, loans from development finance institutions and development assistance for the poorest countries. We are also exploring innovative financing tools, and have initiated discussions with several private banks, impact investment funds and development agencies in support of healthcare systems strengthening activities. Some of these players have already indicated a great level of interest.

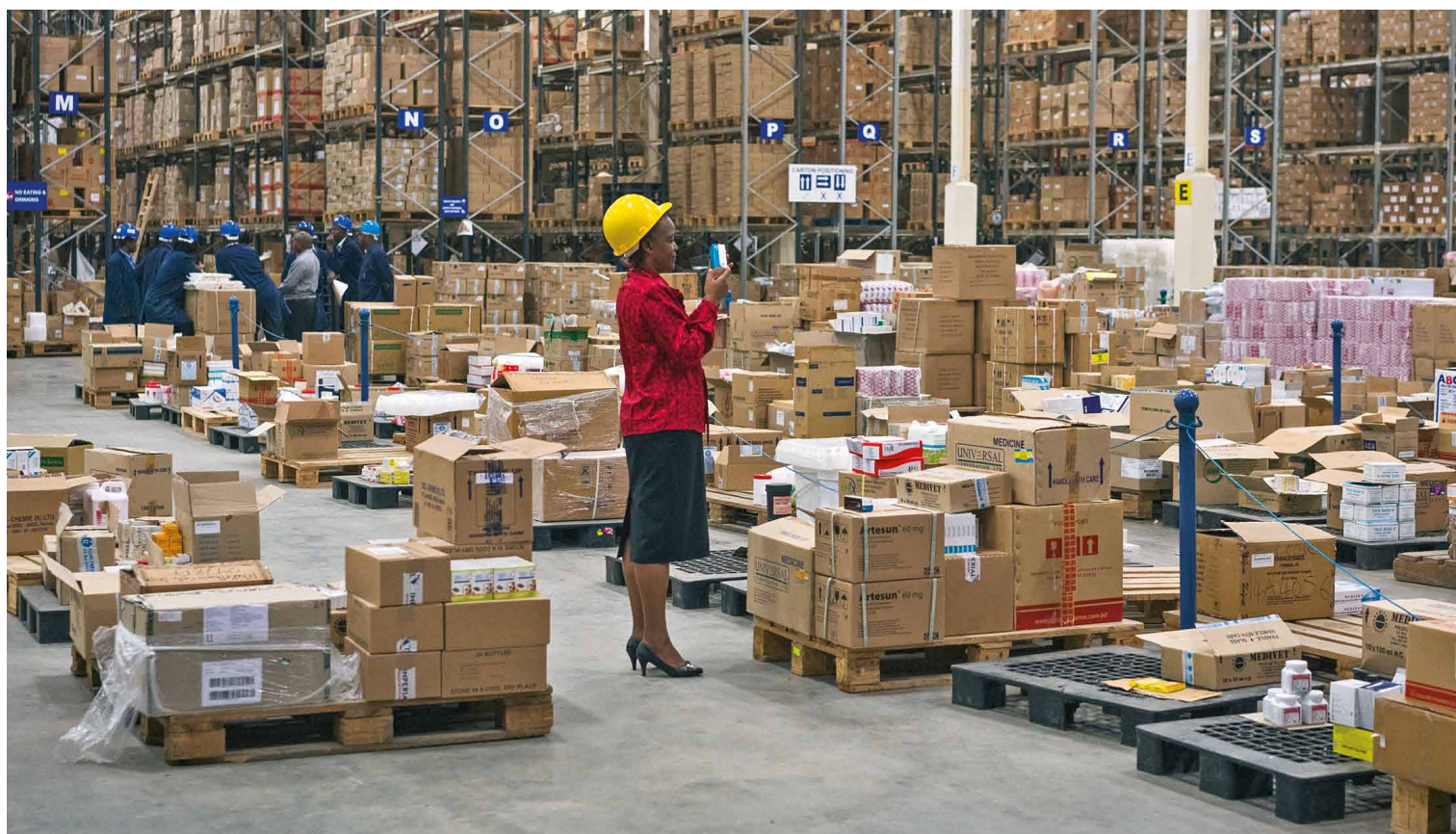
Countering skepticism

When we launched Novartis Access, there was skepticism and questions from stakeholders on our company's true motivation. There was, and still is today, a concern that we would be piloting the program in several countries, but may withdraw if we cannot break even quickly enough. An associated concern was that we may suddenly increase the price of the treatments in the portfolio. Every memorandum of understanding we sign with a country runs for five years, and we will maintain the price of USD 1 per treatment per month for the duration to allow healthcare systems to plan expenditure predictably.

While the program is loss-making at this stage, we hope to break even or make a small profit mid-term, due to the large number of patients living in lower-income countries. We are currently in discussions with more than 10 countries, which will grow exponentially in the future. Our goal is to establish a strong presence there as part of our strategy for growth.

¹ Bloom, D.E et al. The Global Economic Burden of Noncommunicable Diseases, Geneva, World Economic Forum, 2011

² Nugent R.A and Feigl A.B. Where Have All the Donors Gone? Scarce Donor Funding for Non-Communicable Diseases, Centre for Global Development, Working Paper 228, 2010



Another area of skepticism relates to our manufacturing capacity and our ability to meet the demand for Novartis Access products. Achieving our ambition to treat 20 million patients with chronic diseases by 2020 means we will need to supply more than 5 billion tablets per year to these markets. This will require us to increase efficiency in our production and supply network.

Internal challenges

Internally, aligning a program such as Novartis Access with the standard commercial operations of our company is challenging and requires substantial cross-divisional collaboration. This ranges from allocating manufacturing capacity to dedicating sufficient resources to run activities such as regulatory submissions.

Intense discussions took place on how we could operate Novartis Access without running the risk of negatively impacting our core business in developing countries. In some countries, we are trying to build a new commercial business as well as a social business using the same products. Can this work?

There was also concern about the robustness of demand forecasts emanating from countries purchasing the portfolio – which could lead to a situation where we are taken off guard and have to manufacture and deliver drugs in massive quantities within very short timeframes.

Further, our company could be held accountable for activities that go beyond delivering affordable medicines – such as training of healthcare personnel to diagnose and treat NCDs, or developing efficient healthcare systems and distribution channels. Criticism for not doing enough and “only” addressing affordability was also likely.

The price of USD 1 per treatment per month was perceived as a risk and in particular our ability to maintain this price in the future.

These are all valid questions and while we do not have answers to all of them, there is an increasing understanding internally that Novartis Access has been designed as a scalable business model that will create value for society and contribute to the long-term success of our company over time.

Only what gets measured gets managed

Novartis Access will be independently assessed by a team at Boston University. This research will reveal what works well and what doesn't, helping us improve our program.

The team at Boston University developed a methodology to evaluate Novartis Access in Kenya. The methodology was presented to a broad range of stakeholders, including global health experts, academics specialized in the field of measurement and industry representatives. From the start, the process was inclusive and the methodology available online for comment and input.

Overall, the study is intended to evaluate how Novartis Access impacts the availability and price of the medicines included in the portfolio and their therapeutic equivalents.

The results of this study – both positive and negative – will inform the program and our stakeholders. We also hope they will provide valuable learnings for public health experts, global donors, academia and other companies aiming to launch similar programs. Boston University will publish all methods, protocols, instruments and results openly on their website. We are convinced that this level of transparency and the involvement of academia is key to credibility.

The first baseline study was conducted in Kenya in 2016. This study will be followed by a mid-point

evaluation in 2017 – with first results available in late 2017 – and an end-point evaluation in 2018. Other field-based studies will be run in selected countries where Novartis Access is rolled out.

First baseline study

The baseline study, conducted in eight counties in Kenya in 2016, showed strong NCD prevalence variations between counties as well as considerable variations in the number of patients treated for NCDs. The availability of NCD medicines at public and private non-profit facilities was uneven, with some medicines available in up to 60% of facilities, with others available in less than 20%.

About 60% of individuals diagnosed with and prescribed medicine for one of the NCDs in scope had the medicines available in their home. The proportion of household health expenditure on medicines was high and accounted for around 75% of all household health spending.

Detailed results will be published in early 2017 after validation by Boston University.

Evaluation process

1 The evaluation will assess the availability and price of Novartis Access medicines and their therapeutic equivalents in public and private non-profit health facilities and in households, where levels of expenditure on medicines will be explored.

2 The evaluation will assess the awareness of medical personnel and patients for Novartis Access medicines and how this awareness may potentially impact their behavior.

3 The evaluation will gauge the availability and the price of therapeutic equivalents of Novartis Access medicines at for-profit drug sellers to better understand whether and to what extent our intervention impacts availability and price in the private sector.

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Interview with Professor Richard Laing

Richard Laing, Professor of Global Health at Boston University, is leading the team which is evaluating the impact of Novartis Access in Kenya.

1. Why do we need to evaluate Novartis Access?

Evaluation is important for several reasons. Key benefits include demonstrating the program's impact to all actors involved, strengthening its quality and improving outcomes, and avoiding inefficiencies by investing in a program that achieves its objectives. Importantly, lessons learned from Novartis Access will help to design other successful access programs.

2. What are the challenges of evaluating Novartis Access?

There are a series of challenges in conducting rigorous evaluations of access-to-medicine programs. One important challenge is to roll out the program as quickly as possible without knowing the exact situation on the ground. Without baseline information, it is difficult to determine the true impact of a program. Another key challenge is the cost of evaluation. This is why it is important to view evaluation costs as an investment in future benefits rather than as a loss: the results can help to improve the program and reduce future spending on ineffective activities. Evaluations are public goods, and major public and philanthropic institutions often provide grants to support private entities to properly evaluate their programs. In this way, it is possible to share the evaluation costs. In the case of Novartis Access, costs are borne by Novartis alone.

Finally, there may be concerns that an evaluation may show negative outcomes which would affect the reputation of the implementing organization. My view is that companies are likely to improve their reputation by undertaking evaluations in a transparent fashion, so that any program which has a negative effect can be stopped before causing harm or waste.

3. How can Boston University measure the impact of Novartis Access? What does the methodology look like?

Novartis Access has a clearly defined objective: to improve access to a portfolio of medicines for patients diagnosed with one of the following types of NCDs: cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer. By measuring the availability, price and expenditure on NCD medicines at the facility and household level before, during and after the implementation of Novartis Access, Boston University will assess whether the program has achieved its desired outcomes.

“As part of this project, Boston University is developing a robust methodology for evaluating Novartis Access that other access programs can use to assess their programs.”



4. What makes this work different from existing or past measurement efforts?

Previously process rather than impact evaluations were used to determine the benefits of a program. A process evaluation assesses whether a program proposal was implemented as planned (e.g. whether the target population was reached) and determines the major opportunities and challenges in the implementation process. In contrast, an impact evaluation determines whether, and to what extent, the program has improved key performance and population indicators. Impact evaluations have the added advantage of highlighting how different population subgroups might be affected, e.g. low-income versus high-income households, rural versus urban areas, etc. Boston University is conducting an outcome and impact evaluation of Novartis Access, using a cluster-randomized trial design to assess whether and to what extent the program has an effect on the availability and affordability of NCD medicines by household income group.

Another unique aspect of the evaluation of Novartis Access is the monthly follow-up of households and facilities after the baseline study (conducted in August and September 2016 in Kenya) for the duration of the study to monitor and evaluate changes in availability, price and affordability of medicines using an interrupted time series methodology. This is done with telephone interviews. Monitoring over time increases the chances of detecting changes.

The evaluation is transparent to outside scrutiny: the protocol, data collection instruments, results and eventually the data itself, are publically available, as is the agreement Boston University signed to partner with Novartis (sites.bu.edu/novartisaccessevaluation).

5. Beyond Novartis Access, how will this work benefit the broader field of impact measurement?

A recent review of over 100 pharmaceutical industry-led access-to-medicine programs found that the quality of existing evidence on outcomes and impacts is very low. As part of this project, Boston University is developing a robust methodology for evaluating Novartis Access that other access programs can use to assess their programs. In addition, the results of our work will provide valuable lessons as to whether providing a portfolio of NCD medicines at a reduced price can achieve positive outcomes for patients most in need.

Key Performance Indicators (KPIs)

Key Performance Indicators	Sep – Dec 2015	Jan – Dec 2016	Aggregated numbers or period-end information	Comments
Number of submissions / approvals for Novartis Access products	41 / 12	329 / 72	370 / 84	
Number of new countries in which Novartis Access products are submitted*	9	12	21	
Number of new countries with which a memorandum of understanding has been signed*	2	1	3	Kenya, Ethiopia and Rwanda
Number of new countries in which Novartis Access products have been made available*	1	2	3	Kenya, Lebanon and Ethiopia
Number of monthly treatments	39 985	84 448	124 433	
Number of patients reached with Novartis Access products ^{1*}	3 397	8 470	11 867	
Number of facilities in country receiving Novartis Access products	0	50 faith-based facilities 6 county MOH	56	Kenya
Number of new partnerships ^{2*}	1	6	7	Faith-based organizations, nongovernmental organizations, academia, research
Expenditure for capacity building activities ³ (in USD)	0	568 000	568 000	Training, disease awareness, community empowerment; supply chain strengthening; research and impact study
Number of FTEs ⁴ working on Novartis Access*	10	14	14	

* Externally assured

¹ The patient number was calculated based on treatment delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (as it is common for NCD patients to take several drugs). The treatment adherence and treatment overlap factors are based on assumptions from developed markets and will be revisited when we gain additional insights from Novartis Access roll-out countries.

² Partners are defined as those with whom Novartis Access has signed a memorandum of understanding.

³ Capacity building includes activities that either relate to knowledge increase or development of physical capacity and capabilities in public healthcare systems and institutions (scaling up of diagnostics tools, disease awareness programs, healthcare provider training and the development and implementation of NCD guidelines, research, etc.).

⁴ Full-time equivalent positions and contractors.

Independent Assurance Report on Novartis Access 2016 One-Year Report

To the Board of Directors of Novartis AG, Basel

We have been engaged to perform assurance procedures to provide limited assurance on selected data of the Novartis Access 2016 One-Year Report of the company and its consolidated subsidiaries (Novartis Group).

Scope and Subject matter

Our limited assurance engagement focused on selected Novartis Access (NA) indicators for the period starting in September 2015 and ending as of December 31, 2016 as disclosed in the Novartis Access 2016 One-Year Report:

- a) The following NA key performance indicators as disclosed on page 22 of the Novartis Access 2016 One-Year Report:
 - Number of new countries in which NA products are submitted
 - Number of new countries with which a Memorandum of Understanding has been signed
 - Number of new countries in which NA products have been made available
 - Number of patients reached with NA products
 - Number of new partnerships
 - Number of FTEs working on Novartis
- b) The management and reporting processes to collect and aggregate the selected NA indicators as well as the control environment in relation to the data aggregation.

Criteria

The reporting criteria used are described in Novartis Group internal reporting guidelines and define those procedures, by which the NA indicators are internally gathered, collected and aggregated.

Inherent limitations

The accuracy and completeness of the NA indicators are subject to inherent limitations given their nature and methods for determining, calculating and estimating such data. Our assurance report should therefore be read in connection with Novartis Group guidelines, definitions and procedures on the reporting of its NA indicators.

Novartis responsibilities

The Board of Directors of Novartis AG is responsible for both the subject matter and the criteria as well as for selection, preparation and presentation of the information in accordance with the criteria. This responsibility includes the design, implementation and maintenance of related internal control relevant to this reporting process that is free from material misstatement, whether due to fraud or error.

Our responsibility

Our responsibility is to form an independent opinion, based on our limited assurance procedures, on whether anything has come to our attention to indicate that the NA indicators are not stated, in all material respects, in accordance with the reporting criteria.

We planned and performed our procedures in accordance with the International Standard on Assurance Engagements (ISAE) 3000 (revised) 'Assurance engagements other than audits or reviews of historical financial information'. This standard requires that we plan

and perform the assurance engagement to obtain limited assurance on the identified NA indicators.

A limited assurance engagement under ISAE 3000 (revised) is substantially less in scope than a reasonable assurance engagement in relation to both the risk assessment procedures, including an understanding of internal control, and the procedures performed in response to the assessed risks. Consequently, the nature, timing and extent of procedures for gathering sufficient appropriate evidence are deliberately limited relative to a reasonable assurance engagement and therefore less assurance is obtained with a limited assurance engagement than for a reasonable assurance engagement.

Our Independence and Quality Control

We have complied with the independence and other ethical requirements of the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies International Standard on Quality Control 1 and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

Summary of Work performed

- Our assurance procedures included the following:
- Reviewing the application of the Novartis Group internal reporting guidelines
 - Interviewing associates responsible for internal reporting and data collection
 - Performing tests on a sample basis of evidence supporting selected NA indicator concerning completeness, accuracy, adequacy and consistency
 - Inspecting relevant documentation on a sample basis
 - Reviewing and assessing the management reporting processes for NA indicator reporting and consolidation and their related controls.

We have not carried out any work on data other than outlined in the scope and subject matter section as defined above. We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our assurance conclusions.

Limited assurance conclusion

Based on our work described in this report, nothing has come to our attention that causes us to believe that the data and information outlined in the scope and subject matter section (including the related controls) has not been prepared, in all material aspects, in accordance with Novartis Group internal policies and procedures.

PricewaterhouseCoopers AG



Bruno Rossi



Raphael Rutishauser

Basel, January 24, 2017

