Novartis Access 2017 Two-Year Report

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Novartis Access at a glance

Novartis Access offers a portfolio of medicines to address cardiovascular diseases, diabetes, respiratory illnesses, and breast cancer. The portfolio is available to governments, nongovernmental organizations (NGOs) and other public-sector healthcare providers in lower-income countries at a price of USD 1 per treatment, per month*. The treatments have been selected based on medical relevance: they are either on or pertain to a class outlined in the World Health Organization's Model List of Essential Medicines, or belong to the most frequently prescribed medicines in these disease areas.

Depending on public subsidy levels, patients may either receive Novartis Access medicines free of charge or purchase these medicines at a low price to manage their chronic condition in the long term. For those who need to purchase their treatments, we are working with our partners to minimize markups. Recently, we started to offer Novartis Access treatments to the private sector in some countries.

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

Novartis Access launched in 2015 and we strive to reach 30 countries over the coming years based on government and stakeholder demand. Novartis Access is integrated in Novartis Social Business, a unit which also includes the Novartis Malaria Initiative and the Novartis Healthy Family programs.

* The USD 1 price does not include costs for freight, insurance and potential taxes.

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Reflecting on the first two years

This year, at events and meetings I participated in, the word “disruption” often came up. Although it can be a buzzword, I feel it captures the essence of a business model such as Novartis Access, which is trying to leapfrog the current healthcare paradigm – from traditional transactional management approaches to integrated solutions.

Being a pioneer in a field comes with challenges, as you are threatening an established mindset and model. While we can be proud to have delivered more than 800 000 monthly treatments in four countries and to have submitted 502 products in 24 countries in just two years, the rollout of Novartis Access has not been as swift as anticipated. In 2017, we signed agreements with Pakistan, Uganda and Cameroon within just a few months, demonstrating an extraordinary drive at all levels of the government. We are also in advanced discussions with three Asian countries and seven African countries.

A medicine is only as good as the system that delivers it. This year we continued to expand capacity-building activities to raise awareness about, screen and diagnose hypertension and diabetes; train healthcare workers; and work on supply chain integrity and distribution. We partnered with health authorities to help develop noncommunicable disease (NCD) training curricula and treatment guidelines. A first since our launch, we joined forces with cancer groups across four African countries to provide rapid cancer diagnostics and appropriate care and treatment.

Moving from itemized sourcing to portfolio procurement continues to be the biggest hurdle for countries when it comes to adopting Novartis Access. Further, as purchasing decisions are decentralized in many countries, this causes delays in the program rollout.

Another important learning from our experience on the ground this year is that we need to expand into the private sector at a faster pace. The decision to distribute Novartis Access medicines through public channels was made early on to ensure our treatments reach target populations at affordable prices. However, results from a baseline study conducted by Boston University in Kenya in 2016/2017 underline certain flaws in this logic. While more than 50% of chronic diseases are diagnosed in the public sector, more than 40% of patients actually buy their medicines in the private, for-profit sector. Against this background, we will pilot a new approach in the private sector in the coming months, targeting patients in a vast slum

area around Nairobi, Kenya, who lack private health insurance or coverage. We will do this together with the Abraaj Group, a private equity group investing in programs with social impact.

At a larger scale, starting in January 2018, we will be present in the public and private market in seven countries offering Novartis Access medicines as well as the entire Novartis product range registered locally, either as a portfolio or as itemized products. We hope this enhanced flexibility will enable us to better respond to country requirements across all income levels. In parallel, we will of course continue rolling out Novartis Access to the 30 countries as per our original strategic plan.

When I ask myself why we are not delivering faster on our targets, I wonder (without trying to find excuses) if the targets we set ourselves were achievable in the first place. Or perhaps it is because Novartis Access is an idea whose time has come, so we feel we should move much faster. But as Albert Einstein said, “You can’t solve a problem on the same level that it was created; you have to rise above it to the next level” – and that takes resilience and time.

Every day I meet Novartis associates who are proud of what we are doing. Members of my team deeply believe in the mission of Novartis Access and are incredibly motivated. We are fortunate to have the full support of the company. Now we just have to ensure that we keep learning, keep adapting, and keep going until we deliver on our commitment.

Harald Nusser
Head of Novartis Social Business

"If you're a pioneer in a field, you have to live with criticism. This applies to our Novartis Access program. It's not just others in the industry we are competing with; to a certain extent, we are also competing with ourselves.

The hurdles are bigger than we had imagined and the program uptake is not as swift as anticipated. But we remain true to our commitment and see Novartis Access as a contribution to providing lower-income countries with access to essential, affordable medicines. We are experimenting with this program and I hope others in the industry will try out bold approaches as well. We still don't have the ultimate solution, but we can't afford to wait."

Joerg Reinhardt, Chairman of the Board of Directors, Novartis

2017 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

502
Product submissions in 24 countries since 2015

809 666
Monthly treatments delivered since 2015

30
Countries targeted over the coming years

249
Healthcare facilities receiving medicines in Kenya

Learnings and challenges

Professor Vikas Tibrewala and professor Jean-François Manzoni took a deep dive into the first 18 months of Novartis Access, including exploring challenges facing the program. The following is an excerpt from the case study they are currently developing, soon to be published by IMD.*

A major area of concern was the across-the-board USD 1 price, which was based upon a **portfolio approach**. It was hoped that procurement agencies would buy a "reasonable" selection of drugs, rather than just cherry-pick the best "deals" (choosing those with the highest price advantage versus competing suppliers). From the Novartis point of view, this balance between relatively inexpensive drugs such as those for hypertension would compensate for the more sophisticated and expensive drugs in the portfolio. The equilibrium across the medicines on offer was critical to the long-term sustainability of the Access program.

However, this portfolio approach, rather than a molecule-by-molecule approach, posed a set of implementation hurdles for procurement agencies, NGOs and government clinics.

First of all, in order to boost transparency and avoid the perception of bias or corruption, many countries had built very elaborate rules and regulations around the purchasing process to be followed in major drug tenders. Most of these explicitly required molecule-by-molecule tenders, and required the agency to buy the cheapest drug, provided the supplier met the necessary qualifications.

Second, actual purchasing decisions were often made at regional or local levels, rather than at the national procurement level, although this varied by country. In Kenya, many of these local healthcare agencies felt that they would find it very hard to justify the perception of "over-paying" for a drug that they were already used to purchasing, simply to get a benefit on another drug. Thus, even if the intellectual and economic argument added up, some felt that it would be a tough policy to implement.

Third, and perhaps the most challenging obstacle, was that many patients in Kenya paid for their drugs "out of pocket," thus making them very sensitive to price differences. Therefore, if a Novartis Access drug was seen as being more expensive at the patient level, the patient would simply not switch from their usual drug. Thus, even if the agencies bought a bundle, there was a real risk that they would be left holding stocks of unsold drugs.

The "out-of-pocket" or "self-pay" nature of healthcare systems in most low- and middle-income countries presented other challenges as well. First, many patients suffered from more than one disease. For example, it was quite common for a patient with hypertension to also be diagnosed with diabetes. In addition, patients with specific health factors, or with an advanced disease, often required a "cocktail" of drugs, meaning that a given patient could easily be required to consume two, three or even more of the Access drugs, with the commensurate impact on total cost.

How Novartis is addressing the issue

Already in our first year of operation, we understood that we needed to adapt our portfolio offering to meet local requirements. We have made progress with several countries this year. In Rwanda, the government has decided to issue a portfolio tender; and Ethiopia is exploring a similar approach that would also include capacity-building activities.

While it is important to maintain a commercial balance between cost and value, there is enough flexibility to maintain the USD 1 price per treatment per month for subsets of the portfolio or to adjust the price depending on the selected products. Further, starting in January 2018, in seven countries, Novartis Access will be able to expand its offering to also include the entire Novartis product range registered locally, either as a portfolio or as single products in the private market. We hope this enhanced flexibility will enable us to better respond to country requirements.

* IMD-7-1941, Novartis Access: Transforming the Healthcare Challenge in Africa and Beyond (www.imd.org)

A related but separate challenge was a decision by Novartis management to **restrict supply to the public or quasi-public sector only**; the pure private sector would have no access to Access.

The main reason for this exclusive reliance on the public sector was a desire to control markups and the end-user price, as well as to minimize the risks of spillover to less needy segments of the population, thereby ensuring maximum impact without running the risk of negatively impacting the core business.

The problem of hefty markups in the distribution chain was prevalent across Kenya and the rest of Africa. These markups, which could easily be in the range of 300-400% or even more, resulted in prices of drugs in Africa often being higher than anywhere else in the world, and even more so when scaled for purchasing power parity (PPP). Novartis Access aimed to avoid this behavior by working only with carefully selected partners, who committed contractually to ensuring that end-user prices would typically not be more than 50% above the Novartis price of USD 1.

However, this decision presented a couple of problems. First, in Kenya for instance, even though the public sector and the faith-based facilities tried to cover a large number of Kenyans, many still relied on the proximity and ubiquity of the private pharmacies. Second, many observers feared that there would be "leakage" in that the more attractive drugs would find their way to the private sector anyway, where they would be sold for higher prices, but would still be lower than the non-Access price.

How Novartis is addressing the issue

Initially, the strategy of Novartis Access was to focus on distribution through the public sector before expanding into the private sector. Learnings from the ground, underlined by the results from the Boston University baseline study in Kenya, show that although the majority of NCDs are diagnosed in the public sector, close to half of the patients buy their medicines in the private, for-profit sector.

Starting in January 2018, Novartis Access will continue to be rolled out as planned in the public sector, but we will also test a new approach in the following seven countries: Cambodia, Laos, Malawi, Nepal, Rwanda, Tanzania and Uganda. There, Novartis Social Business (which comprises Novartis Access) will be responsible for the entire Novartis offering, including the Novartis Access portfolio, sub-portfolios, and single products both in the public and in the private sector. This approach will allow us to tailor our offer to the specific healthcare needs of these countries. Ultimately, the goal is to maximize patient reach across all income levels to ensure a sustainable business.

Further, our agreement with Greenmash in Pakistan will use biometric information to ensure that Novartis Access medicines are made available to the patients included in the prime minister's national health insurance program. The system will also enable accurate stock management from warehouse to dispensing clinic, ensuring transparency in the supply chain.

Experience on the ground so far shows that patients pay around USD 1.5 per treatment per month out of pocket.

While affordability of medicines was indeed a major problem, it was also understood that a focus on price alone would be an incomplete response to the NCD challenge. Given the historic focus on infectious diseases, the healthcare systems in many low- and middle-income countries were simply not geared up to appropriately diagnose and treat NCDs. This meant that **capability building** was at least as critical as appropriate pricing. Large-scale capability building required large-scale resources, and it was unlikely that Novartis could pull this off alone. Thus, Novartis was actively working on building appropriate partnerships with NGOs and other potential partners, but the question remained: Would this be enough? Also, some executives as well as industry experts wondered where the line should be drawn in terms of shared responsibility.

In the area of diagnosis and treatment, Novartis was up against a problem unique to NCDs that had been faced everywhere in the world, even in the most advanced countries. The vast majority of NCDs do not come with major "ill health signals" for patients. Thus, increasing awareness and education for patients as well as healthcare professionals was critical to ensuring early diagnosis, which itself was critical to saving a patient's life, or at a minimum, her or his quality of life.

How Novartis is addressing the issue
Since launch, we have signed 13 capacity-building agreements.

Capacity-building activities to screen and diagnose people for diabetes and hypertension have started in Kenya and Cameroon. We have also joined forces with partners in several countries to launch awareness campaigns encouraging individuals to know their critical health numbers. Further, we are supporting trainings on NCD screening, diagnosis and treatment for healthcare professionals. We also support training of emerging leaders globally with the World Heart Federation to form experts who collaborate, research, and advocate to reduce premature death from NCDs.

In the field of cancer care where no broad coalition currently exists in Africa, we have started collaborating with two organizations across Ethiopia, Rwanda, Tanzania and Uganda: the American Society for Clinical Pathology and the American Cancer Society. These collaborations aim to help strengthen the continuum of care for cancer patients, from training for better diagnosis and care, to improved access to treatment, through to advocacy for national cancer treatment guidelines.

Another area that concerned stakeholders, internally and externally, was the potential **scale of the market** if the program proved successful. While this might be considered a "problem we would love to have," it could nevertheless pose a challenge. Kenya was a country of 45 million people; Ethiopia was even larger, with a population of almost 100 million; and Vietnam brought another 90 million people to the mix. Thus, looking at just the first three countries, Novartis Access was already faced with a potential market of 200 million. The dilemma was: Either Access would not reach a large percentage of the target population and thus have limited impact; or it would succeed, thus posing a major challenge to the Novartis supply chain and production capabilities.

Therefore, if Access were to achieve dramatic success, the production capabilities would be stretched to the limit and require major investments to meet the new demand. Nevertheless, many executives felt that this was a manageable hurdle and, just like for malaria, Novartis would rise to the occasion.

How Novartis is addressing the issue
We are only two years into the program. It is therefore too early to determine if production capability could potentially be a challenge, but we are confident we will be able to meet the demand.

Two years into the program: Country updates

Cameroon

In September, Cameroon became the sixth country to sign an agreement to implement Novartis Access. First treatments were delivered in June.

Chronic diseases cause 31% of deaths every year in Cameroon, and there is a 20% probability of dying between the ages of 30 and 70 from one of the four main NCDs in Cameroon – one of the highest rates in sub-Saharan Africa.[1]

[1] WHO: http://apps.who.int/iris/bitstream/10665/128038/1/9789241507509_eng.pdf

Initially, Novartis Access medicines will be available through the 88 hospitals and clinics of the Cameroon Baptist Convention Health Services (CBCHS), which are spread across six of the country's 10 regions. From 2011 to 2015, NCD consultations recorded at seven CBCHS facilities increased by more than 40%.[2] The program will be extended to other faith-based organizations and eventually to the entire country.

By working with faith-based organizations and other public sector players, we expect to reach a significant number of low-income patients in Cameroon given that 90% of the population accesses healthcare through public and faith-based channels.

Beyond medicines, the collaboration includes activities to strengthen healthcare systems, for example by training healthcare professionals on NCD management and by providing community education and awareness. In September, CBCHS and Novartis kicked off a Know Your Numbers campaign to encourage individuals to know their critical health numbers. The campaign will take place in seven health districts over the next two years, potentially reaching a total of 1 million people. Nurses from CBCHS facilities have also been trained on NCD screening, diagnosis and treatment. In addition to capacity-building activities in these two areas, we will work on supply chain integrity and distribution.

[2] Noncommunicable disease trends and access to care in seven facilities of the Cameroon Baptist Convention Health Services: a situational analysis. Clinical Research and Education Consultancy, Yaoundé 2016

"A patient was very ill with malaria. While being treated, it became clear that she also had very high blood pressure, and she was referred to my clinic. There she was examined, given lifestyle advice, and prescribed tablets to lower her blood pressure.

Six months later, her blood pressure was still sky-high. I asked her about the tablets. She said, 'Well, doctor, I took one tablet and then I felt fine – so I didn't take any more.'

This shows how far we have come in the fight against NCDs and how far we have to go."

Samuel Kingue, executive president, Cameroonian Society of Cardiology

Ethiopia

Plans are underway to start capacity-building activities related to asthma, diabetes, hypertension and oncology. Further, Novartis Access is in discussions with the Ethiopian Orthodox Church and the Ethiopian Catholic Church to strengthen the supply chain and improve drug provision. The Catholic Church has a very large reach in the country, providing treatment to about 6 million people each year. We are also in advanced discussions with the Ethiopian Red Cross to procure Novartis Access medicines and set up capacity-building activities.

In November, Novartis Access, the American Society for Clinical Pathology, and the American Cancer Society joined forces to improve cancer diagnosis and care in lower-income countries.

In Ethiopia, the program will be rolled out in the Tikur Anbessa (Black Lion) Hospital in Addis Ababa, and in the Ayder Referral Hospital in Mekele.

Novartis Access, the American Society for Clinical Pathology, and the American Cancer Society have teamed up to devise a common approach to manage cancer in lower-income countries. These activities complement the work the Clinton Health Access Initiative is doing to improve access to affordable, quality-approved oncology medicines in Africa.

Funded by Novartis, the collaboration will include building healthcare capacity for immunohistochemistry analysis in six hospital laboratories in Ethiopia, Rwanda, Tanzania and Uganda. Further, training of healthcare professionals will be organized in the same four countries to ensure quality processes in the transportation of biopsy samples and the administration of chemotherapy. The objective is to provide patients with rapid cancer diagnostics and appropriate care and treatment. Both are crucial pillars to help countries address cancer care.

Through these partnerships, several steps are addressed in the continuum of care – ranging from training to improve diagnosis and access to treatment, to advocacy for national cancer guidelines.

We interviewed Khawar Mann, CEO of the Abraaj Growth Markets Health Fund (AGHF), a private equity group investing in programs with social impact partnering with Novartis Access to pilot a new approach in the private sector that targets patients in Kenya without private health insurance or coverage.

What innovative financing approaches exist to fund NCD care in low- and middle-income countries?

The chronic nature of NCDs defies short-term, charitable endeavors. Instead, lasting solutions require ongoing engagement with individual patients and the health systems that serve them. We need to address this challenge by building a continuum of care that provides everything from community interventions to complex tertiary treatments, thereby ensuring patients receive appropriate, cost-effective treatment at each stage of care. By investing up front in a comprehensive ecosystem that offers education, early detection and prevention at every level, patients can proactively manage their health and minimize or prevent long-term, catastrophic outcomes.

One way to galvanize the capital required for long-term comprehensive solutions is to pool private capital from various sources to tackle a systemic challenge at scale. This is what we call partnership capital. Private equity can play a leading role as we have done in AGHF bringing in capital from foundations and strategic corporates who can also pool their combined expertise in tackling a given issue. The key is to build a structure whereby financial returns can be achieved for investors while placing impact on the same footing. Addressing healthcare systems at a national or regional level rather than investing in individual assets is critical. Taking a system-wide approach allows for scale and brings delivery costs down.

Do you see a role for the private sector beyond the traditional provision of goods and services to improve healthcare in low- and middle-income countries?

The mounting burden of NCDs in growth markets is often overlooked by governments and donors still struggling to manage the acute, highly visible health problems caused by communicable diseases. The private sector, which has both the expertise and commercial incentive to address NCDs, needs to step up and direct its time, attention and resources to this gathering crisis. One major way in which the private sector can contribute to better long-term outcomes in the NCD space is through data collection and analysis. As of today, very little is known about NCD patients in growth markets.

This gap in knowledge creates a need for data, which in turn creates business opportunities for those seeking to develop and test new products, services and interventions. At the same time, this privately collected data can also provide public value by enabling governments and donors to fully understand the depth and breadth of the NCD challenge within their jurisdictions. By providing its public sector counterparts with insights from its independently gathered data, the private sector can help chart a path toward more efficient, cost-effective solutions.

Moving forward, what should Novartis Access change or improve?

In addition to collaborating with non-traditional partners whose patient base fits with the mission of Novartis Access, the program should consider putting more emphasis on early detection and intervention. The majority of NCD patients in the markets where the program operates are not correctly diagnosed; remedying that would expand the patient base and also minimize long-term health costs.

"The United Nations High Commissioner for Refugees and its partners – such as the Kenya Red Cross – take care of refugees' needs including healthcare based on available resources and priorities. Yet chronic diseases, which are silent killers, have not been seen as a priority for refugee populations until now. This has led to major gaps in terms of access to preventive NCD care and treatment in camps. It is now time to take action."

Sylvia Khamati, head of health and social services, Kenya Red Cross

Kenya

The Kenya Red Cross Society (KRCS) is a key partner to deliver high-quality NCD care for some of Kenya's most vulnerable populations. The organization serves approximately 80 000 refugees in the Dadaab camps alone. In 2017, with grant support from Novartis, KRCS conducted community disease awareness sessions as well as training for community health volunteers and healthcare providers at its level 5 hospital in Dadaab. The intent is to build an integrated model of care for diabetes, hypertension, asthma and cardiovascular disease.

In the first three months of implementation of the project, 368 people were screened in the camps, with 69 enrolled for further treatment and management. Care is comprehensive, involving education, counseling, and provision of affordable treatments. Additionally, widespread community sensitization sessions targeting religious leaders, youth groups and general community members were conducted. Trainings for healthcare providers based on the NCD management guidelines from the Ministry of Health continue to be rolled out.

This partnership demonstrates the exemplary aspects of working with NGOs to provide access to medicines. Gaps in healthcare for vulnerable populations are addressed, and implementation lessons can be applied to scale up for larger populations.

To date, more than 360 000 Novartis Access treatments have been imported through the Mission for Essential Drugs and Supplies (MEDS).

Throughout 2017, Novartis Access has been actively supporting the Ministry of Health to update national treatment guidelines on diabetes and cardiovascular diseases, bringing them in line with recommendations from the World Health Organization. The team has also been working with the ministry to harmonize the NCD training curriculum, which is now available for use with healthcare workers. Last but not least, together with partners, Novartis Access provided input into the national cancer strategy launched in July that lays out a roadmap in the fight against cancer in Kenya. A total of 10 counties and 136 faith-based facilities are now distributing the products. We also signed memoranda of understanding with two counties to provide treatments, screening and capacity building.

Delivering training on NCD care to partners
In partnership with the Ministry of Health, approximately 40 "train the trainer" sessions were held in 2017 to increase NCD screening capacity (these sessions included 15 with the Christian Health

Association of Kenya, 12 with the Kenya Conference of Catholic Bishops, and 10 with the Red Cross in the Kakuma and Dadaab refugee camps). Partners are now using this training to train their own healthcare workers. The improved screening capacity has led to an increase in patient referrals as well as empowerment of diagnosed patients who become health advocates themselves. Some of them have even launched patient groups.

As part of the continuous medical education Novartis Access offers, 40 healthcare workers from partner organizations also attended a conference on asthma and chronic obstructive pulmonary disease (COPD), an obstructive lung disease.

A challenging year
Despite much progress, 2017 was a challenging year for Novartis Access in Kenya. It is taking more time than anticipated to implement the Novartis Access portfolio approach in the public sector, partly because the national procurement system is still tender-based.

Further, the country underwent several strikes from doctors, nurses, clinical officers and pharmacists, critically hampering healthcare delivery in the public sector. This was compounded by the tensions surrounding the protracted presidential election. Some county governments are indebted and not able to procure medicines from MEDS.

Moreover, as in several other African countries, awareness about NCDs remains low and there is a lack of specialized doctors, requiring leapfrogging medical training and scaling up diagnosis and screening to better manage NCDs. There also is a need to upgrade treatment guidelines on diabetes and hypertension, and to train healthcare providers on newer therapeutic options to treat these conditions.

Lebanon

From April 2016 to April 2017, Novartis and the International Committee of the Red Cross (ICRC) worked together on a pilot to provide Novartis Access medicines for hypertension and diabetes to Syrian and Palestinian refugees as well as vulnerable Lebanese populations in 10 ICRC-supported primary healthcare facilities in Lebanon. There is a strong unmet need for these medicines among these populations, and we want to ensure that patients have access to healthcare services and treatments. The initial lessons learned re-emphasized the need to clearly define roles and responsibilities for public-private partnerships in humanitarian settings, as well as to better understand the very unique barriers for access that exist in complex protracted crisis environments.

Moving forward, Novartis and the ICRC will explore multi-stakeholder approaches to best tackle the management of NCDs in humanitarian settings.

Pakistan

In May, we signed a memorandum of understanding with the Ministry of Health to implement Novartis Access in Pakistan. Through this agreement, medicines will be made available free of charge to the poorest population through selected hospitals under the prime minister's national health insurance program – first in Islamabad and over time in all provinces. Overall, the program aims to serve 100 million poor patients, and nearly 1 million families are currently enrolled.

As responsibility for healthcare is decentralized, we also signed an agreement in November with the province of Punjab, the country's most populous province with more than 110 million inhabitants. Medicines will be provided free of charge through

public sector hospitals in Punjab from early 2018 onward. Discussions are also taking place with the province of Khyber Pakhtunkhwa.

The world's sixth most populous nation, Pakistan is among the countries most impacted by NCDs. It is facing rising rates of diabetes, obesity, heart disease and other NCDs, which are disproportionately affecting poor families and worsening the burden of poverty. Chronic diseases currently account for 59% of the total disease burden in Pakistan,[3] and there is a 21% probability of dying between the ages of 30 and 70 from the four main NCDs.[4]

[3] Engelgau MM, El-Saharty S, Kudesia P. Capitalizing on the Demographic Transition: Tackling Noncommunicable Diseases in South Asia. World Bank, Washington DC, 2010.
[4] WHO Global Status Report on NCDs 2014: http://apps.who.int/iris/bitstream/10665/148114/1/9789241564854_eng.pdf?ua=1

When implementing Novartis Access on the ground, we will need to ensure that the program reaches the right patients and that we are able to measure impact across key indicators. To address these challenges, we have entered into a partnership with Greenmash to develop an IT system to register patients and track medicine dispensing. This will provide essential, anonymized data to enable accurate stock management from warehouse to dispensing pharmacies. An offspring of our SMS for Life platform, the system will be implemented first in Punjab using biometric information to ensure medicines reach eligible patients.

The Drug Regulatory Authority of Pakistan has granted permission to Novartis Access to register its products using the fast-track approval process designed for patient access programs in the country.

"Noncommunicable diseases will sooner or later overwhelm the existing health system capacities unless rapid investments are made in disease prevention and health promotion. An NCD unit is fully functional in the health ministry at federal level and we are working closely with the provinces to contain the spread of noncommunicable diseases. Having access to high-quality treatment at low cost is a critical part of our work to lessen the impact of chronic diseases. Under the prime minister's national health program, Pakistan is taking strides in providing free treatment to millions of families through both public and private health facilities. We do not believe in hollow slogans or mere campaigning. We believe in delivering to the masses."

Saira Afzal Tarar, federal minister for national health services, regulations and coordination, Pakistan

"Today, 25% of Ugandans die from an NCD, and the proportion is increasing every year. Nearly a quarter of Uganda's adult population has raised blood pressure. More than 75% of these people don't know they have a problem and are not on a medication to control their hypertension. The Ministry of Health has established an NCD program to coordinate efforts around prevention and control. But getting the healthcare resources we need for NCDs is challenging given that infectious diseases are still so prevalent. Government resources are limited, so NCDs will also need to fight for their fair share, despite their growing importance."

Prof. Anthony K. Mbonye, director of health services, Ministry of Health, Uganda

Uganda

In June, we signed a memorandum of understanding with the Ugandan Ministry of Health, complementing the government's efforts to improve NCD care. The country has already established dedicated NCD units with heart, lung and cancer institutes.

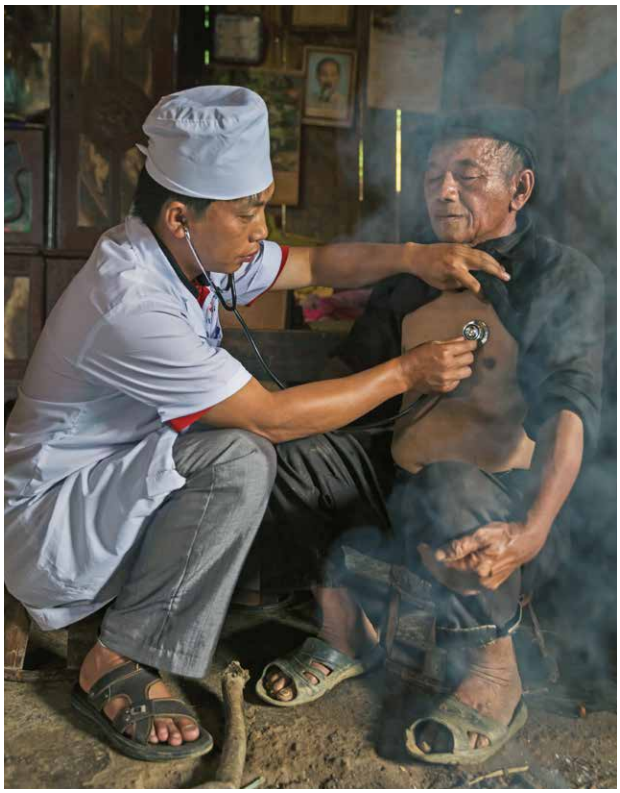
The ministry also provides funding to the private not-for-profit sector, through the Joint Medical Store (JMS), to improve healthcare provision. JMS will distribute Novartis Access medicines expected to hit the ground in early 2018.

This year we also entered into a partnership with the Uganda Protestant Medical Bureau – one of the largest faith-based organizations in the country – to carry out capacity-building and screening programs in 2018. We want to empower village health committees to raise awareness about and screen for basic NCDs such as high blood pressure, providing an early warning and referral system to appropriate levels of care.

Rwanda

Rwanda was one of the first countries to sign a memorandum of understanding to implement Novartis Access. The government has now awarded Novartis Access a portfolio tender and first treatment delivery is expected early 2018. We have also identified partners on the ground – including faith-based organizations and NGOs – to carry out screening programs.

To complement the government's efforts to increase research capacity in Rwanda, we will host workshops to support capacity building in the area of clinical research.



Vietnam

Registration of Novartis Access products is ongoing in Vietnam – the registration process can take up to two years – and we expect to introduce the first two products via our existing Healthy Family program in two provinces in 2018. The objective is to cover the entire basket over time.

In 2017, we developed a methodology to value the social impact of our drugs and applied it to the Novartis Access portfolio in Kenya.

First, we calculated quality-adjusted life-years (QALYs) for each of the products in the portfolio in Kenya over 12 months. One QALY equates to one year in perfect health. Second, we attributed a socioeconomic value to these QALYs for paid and unpaid activities, thereby also factoring in the effects of better health on productive activities outside the labor market. For 2016, we found a social impact value of USD 632 000.

Measuring and valuing the social impact of healthcare products is complex and challenging, as numerous assumptions are required. We will refine these assumptions as we apply our methodology to more products and countries. This activity is part of our financial, environmental and social (FES) impact valuation efforts.

Our partners on the ground

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. We are partnering with organizations that can help strengthen every part of the continuum of care.

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.)	• American Cancer Society (ACS) • American Society for Clinical Pathology (ASCP) • Cameroun Baptist Convention (CBC) • Christian Health Association of Kenya (CHAK) • Kenya Red Cross (KRC) • Kenya Conference of Catholic Bishops (KCCB) • International Committee of the Red Cross (ICRC) • Mission for Essential Drugs and Supplies (MEDS) • Uganda Protestant Bureau (UPB) • World Heart Federation (WHF)
Academia and research	
• Provide necessary transparency in challenging environments • Evidence impact to guide future investment and implementation of access programs	• Boston University (BU) • Duke-NUS Medical School (Duke-NUS) • Management Sciences for Health (MSH)

Interview with professor Richard Laing

Professor Richard Laing and his team at Boston University in the US are evaluating the impact of Novartis Access in Kenya.

You say companies lack proper measurement to evaluate their access-to-medicine programs. What do you mean?

In the past years, pharmaceutical companies have made good progress when it comes to improving access to their medicines, but evaluation is still lacking. Why should you evaluate good work? Also, what people think is good work may sometimes actually not have the desired effect or may cost an enormous amount for a limited benefit.

Further, evaluations are often done as an afterthought. They lack rigor and the methods used are sometimes deficient. For instance, there is no sense in reporting on the communities, patients or facilities that have received the intervention and in ignoring those that have not received it. What is also often overlooked is which households are helped. That's a key part of the process. What we know from other studies is that short-term programs tend to benefit the middle class and not the lower class.

Can you tell us more about the baseline study you conducted in Kenya?

In a nutshell, this study is trying to measure availability and cost of medicines in the therapeutic areas covered by Novartis Access. Importantly, this study is looking at all aspects and all beneficiaries of Novartis Access in Kenya.

Randomized controlled trials are the norm in clinical research, but the principle is often forgotten in evaluation projects. In this study, we pushed very hard to ensure that we included control counties. So far, we've done the baseline in eight counties, and four of these have been targeted to receive the intervention.

Importantly, we didn't just look at the facilities where the medicines are available; we also undertook a baseline survey of households. We powered the study to a level where it's possible to categorize households. Based on the possessions in their houses, we were able to allocate each household to one of five income groups, from the richest quintile to the poorest quintile. What we hope to see is that households in the lowest-income quintiles will have benefited from Novartis Access medicines.

"The question then is should Novartis Access continue to distribute its medicines through public and faith-based facilities or change its distribution strategy?"

What are the other elements the baseline study is trying to measure?

We also compared availability of NCD medicines with treatments against acute infections.

We found an enormous difference in availability between these treatments and between public and private facilities. In the public sector, chronic medicines were available around 17% of the time, while acute medicines were available 58% of the time. In the private sector, the difference was even bigger: Chronic medicines were available 25% versus 72% for acute medicines. I expected some difference but not such a large difference.

The second big surprise was that while more than 50% of cases were diagnosed in the public sector, more than 40% of the patients bought their medicines in the private, for-profit sector. The question then is should Novartis Access continue to distribute its medicines through public and faith-based facilities or change its distribution strategy?

Did you encounter difficulties you didn't anticipate?

We found very substantial variations in the prevalence of treated NCDs in the different counties. While the overall rate for Kenya has been reported at about 20%, we found that it varied from 3% of households to 33%. Three of the counties had a prevalence of only 3-4%, meaning you have to visit 30 households to find one patient with diabetes, high blood pressure or asthma. In other areas, you could visit three households and one of the three would have these conditions. That's a very big difference.

In addition, Kenya is in a dynamic situation at the moment, decentralizing healthcare services to the counties. Before, during and after the baseline study, changes were ongoing in terms of who was paying health workers' salaries, who was delivering medicine, what was the policy of each county as to which medicines would be available for free and to whom. That did affect our study results as well.

Finally, we found that perception was a challenge. If you asked health workers about medicine availability, they would only answer in terms of acute medicines, stating that there was enough availability. And only when asked specifically about NCD medicines would they say that those were unavailable and they had to refer patients to the private sector.

Some health workers were not sure whether they were meant to be responsible for NCD care and treatment. Quite a few did not think so. They felt that people who needed NCD treatments should go to the private sector.

What did the study reveal in terms of product prices and differences in prices?

One finding that is consistent with what has been found in other countries was that the richest quintile and the poorest quintile consistently paid the most for their medicines. Part of the reason is that the poorest people are unable to travel to buy their medicines where they are cheaper. We also found that pharmacies or drug sellers know this and will often charge the poorest the most.

For example, if we look at asthma inhalants, the poorest quintiles were paying nearly USD 6 for inhalants, while the richest were paying USD 3.50 and the second poorest were paying USD 1.50. And when we look at metformin for diabetes, the poorest would pay USD 2.50 for a month of treatment, the richest about USD 2.30, and the mid-quintiles 50 cents. This represents a five-fold variation in price, which is huge.

Is research still ongoing? What are the next steps?

We are currently planning the midline study, for which we will do the second round of qualitative interviews with the same health workers or the same households we interviewed the first time to find out what has changed. How are things different now than they were a year ago before Novartis Access was launched?

We will also try to elucidate further on the price of medicines for low-income quintiles. Are they aware that they are paying more than others for their medicines, or do they just think that that's what the price of the medicine is?

If they don't know, can Novartis Access make information available to those people to encourage them to take advantage of the program? If they do know but can't do anything about it because they can't travel, this will require a different solution.

An endline study is planned for July 2019, and we expect to present the final results in November of that year at the Novartis Access annual stakeholder dialogue and at the World Health Assembly in 2020.

Key performance indicators (KPIs)

Key performance indicators	Jan – Dec 2017	Jan – Dec 2016	Sep – Dec 2015	Aggregated numbers or period-end information	Comments
Number of submissions / approvals for Novartis Access products	**132 / 137**	**329 / 72**	**41 / 12**	**502 / 221**	
Number of new countries in which Novartis Access products are submitted*	**3**	**12**	**9**	**24**	
Number of new countries with which a memorandum of understanding has been signed*	**3**	**1**	**2**	**6**	Kenya, Ethiopia, Rwanda, Uganda, Cameroon, Pakistan
Number of new countries in which Novartis Access products have been made available*	**1**	**2**	**1**	**4**	Kenya, Lebanon, Ethiopia, Cameroon
Number of monthly treatments	**685 233**	**84 448**	**39 985**	**809 666**	
Number of patients reached with Novartis Access products[1]*	**386 463**	**8 470**	**3 397**	**398 330**	
Number of facilities in country receiving Novartis Access products	**249 (Kenya) 6 (Cameroon)**	**56 (Kenya)**	**0**	**255**	Includes faith-based, NGO- and government-run facilities
Number of new partnerships[2]*	**6**	**6**	**1**	**13**	Faith-based organizations, NGOs, academia, research
Expenditure for capacity building activities[3] (in USD)	**1 218 406**	**568 000**	**0**	**1 786 406**	Training, disease awareness, community empowerment; supply chain strengthening; research and impact study
Number of FTEs[4] working on Novartis Access*	**25**	**14**	**10**	**25**	

* 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 the Novartis Access 2017 Two-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 2017 Two-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 ending as of December 31, 2017 as disclosed in the Novartis Access 2017 Two-Year Report:

a) The following NA key performance indicators as disclosed on page 18:
- 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 NA

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 the 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 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 controls relevant to this reporting process that is free from material misstatement, whether due to fraud or error.

Our responsibilities

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 the 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 indicators concerning completeness, accuracy, adequacy and consistency
- Inspecting relevant documentation on a sample basis
- Reviewing and assessing the management reporting processes for NA indicators reporting and consolidation and the 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

Martin Kennard Raphael Rutishauser

Basel, January 23, 2018

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