

Novartis Social Business Report 2018





Contents

| | |
|--|----|
| Foreword: Treating patients not diseases: we need a mindset shift | 3 |
| About Novartis Social Business | 4 |
| Applying learnings from legacy programs and maximizing synergies across activities | 6 |
| Changing the pharma model from the few to the many | 11 |
| 2018 country achievements | 14 |
| Driving scientific innovation to address key healthcare needs | 16 |
| Embracing digital for better health and stronger healthcare systems | 20 |
| Partnering to solve healthcare ecosystem challenges | 24 |
| Measurement and evaluation | 30 |
| Key Performance Indicators (KPIs) | 34 |

Treating patients not diseases: we need a mindset shift

Healthcare, basic hygiene and sanitation remain out of reach for billions of people, disease patterns are shifting, the refugee crisis is unprecedented, the roles of business and civil society are being redefined, and the gap between rich and poor is growing. Recent estimates show that just eight men own the same wealth as the poorest half of the world.¹

Because I am an optimist, my instinctive reaction is to draw opportunities from challenges. The World Health Organization Independent High-level Commission on Noncommunicable Diseases (NCDs) declared that NCD interventions could bring a return of up to USD 7 per person for every dollar invested. This shows that investing in healthcare today is an investment in a sustainable future.

Yet, to grasp these opportunities, we need to change our mindset. We need to take an integrated approach to healthcare. We can no longer only treat diseases; we need to treat patients. For us in the healthcare industry, this means we must look at innovation beyond science and explore novel social business models, if we want to generate scalable health impact. We also need to engage in prevention efforts with partners, so we cover the entire continuum of care.

This is where I believe Novartis Social Business (NSB) has a unique contribution to make. About two years ago, we combined our company's legacy access-to-medicine programs under the NSB unit, placing equal weight on financial and social returns.

This mindset change is required by all of us in the global health community, as we each own a part of the solution to access. The reason is simple: Financing for health is still seen as a cost rather than an investment in economic growth. Unless we put our heads together to change this paradigm, we will fail to deliver on universal health coverage.

I feel these investments should support a patient-centric model, cutting across infectious and chronic diseases in lower-income countries, where healthcare systems are stretched and under-resourced. This is where decentralization of care and strengthening primary healthcare service delivery are key.

This year, in an effort to provide treatment to patients in a sustainable way, regardless of their income, we also started to test a new approach by managing the full Novartis product range in six countries in Africa and Asia.



In this report, we want to show how all our activities build on and reinforce each other.

A key touchpoint is primary healthcare, which is essential to unlock health equality and to close the loop to tertiary healthcare. Yet, while poor patients get diagnosed in public health facilities, most of them buy their medicines in private health facilities, which are usually better stocked but more expensive. This is why we have now started entering the private sector in Cameroon, Kenya, India and Vietnam.

Looking ahead, countries can advance further and faster with digital solutions. These will provide the surveillance systems needed to monitor progress and to surface insights that can help us move toward universal health coverage. The challenge will be to develop a harmonized regulatory environment geared toward these innovations.

We continued to make progress on the measurement and evaluation framework developed with Boston University to assess the impact of our access-to-medicine interventions. I believe such a framework should also apply to nongovernmental organizations, philanthropic organizations and governments to allow meaningful comparisons for impact investors.

As I reflect on 2018, I feel we continue to take unconventional, courageous steps to improve healthcare for vulnerable populations, but we need to do even more. The best solutions will be the ones we co-create with our partners, putting patients at the core.

Harald Nusser
Head of Novartis Social Business

¹ An economy for the 99%, Oxfam: www.oxfam.org

About Novartis Social Business

Novartis Social Business (NSB) supports global public health through novel sustainable business models.

Our activities are rooted in local communities, where we work with partners to provide affordable, high-quality medicines against infectious and chronic diseases while strengthening healthcare capacity.

Everything we do relies on our network of partners, who share our purpose.

NSB comprises access-to-medicine legacy programs (Novartis Access, the Novartis Malaria Initiative and Novartis Healthy Family) supported by digital platforms, and has responsibility for the entire Novartis product range in six countries* in Asia and Africa.

We aspire to become the preferred partner to improve public health in lower-income countries.

*Malawi, Rwanda, Tanzania, Uganda, Laos and Cambodia. Nepal formally transitioned to NSB in January 2019.

6

Of the top causes of deaths in low- and middle-income countries addressed by NSB portfolio

24.8m

Patients reached with medicines in 2018

7.9m

People reached with health education in 2018

651

Full-time equivalent positions and contractors working for NSB globally

Novartis Social Business supports the five strategic priorities of Novartis



Unleash the power of our people

NSB activities support the Novartis purpose to improve and extend people's lives, and contribute to employee satisfaction and retention. In fact, NSB receives numerous unsolicited applications from internal and external candidates on a weekly basis. Further, to succeed in future growth markets, we need to strengthen our understanding of these markets as well as our expertise to bring local activities to scale. NSB therefore offers a key talent development platform for future Novartis leaders.



Deliver transformative innovation

NSB delivers transformative innovation on several fronts. We spearhead new business models to address healthcare system shortfalls or market failures, in ways that also generate societal returns. On the scientific front, our two antimalarials in development could provide new modes of action, reinforcing the leadership role Novartis has played in malaria over the past two decades. We are also exploring innovative financing mechanisms to allow Novartis to scale up health impacts.



Embrace operational excellence every day

As our business is based on a volume approach, seamless collaboration with our global manufacturing organization is key. Further, we also need to optimize the order-to-cash process for export markets and leverage cross-divisional synergies to avoid duplications. Our common packaging approach across countries and our efficient regulatory submission strategies also exemplify our focus on operational excellence.



Go big on data and digital

NSB has spearheaded several digital initiatives to address the shortage of healthcare capacity and to enable fast, reliable and effective processes throughout the continuum of care: SMS for Life in Nigeria, Zambia and soon in Zanzibar; an expanded version of the platform developed for Pakistan (and also offered to Myanmar); and access-enabling digital pilots in India (with TechMahindra), the Philippines and Cambodia (both with Allied World Health).



Build trust with society

NSB collaborates with governments as well as local, regional and international NGOs, academia, foundations, donors and policymakers to generate positive impact. Our work is recognized by independent experts, and we collaborate with stakeholders to establish a robust methodology to evaluate societal returns, helping inform future investment decisions. We are transparent on what is working well and not so well, and where we need to improve our approach. We also share data and insights with other public health actors.



Applying learnings from legacy programs and maximizing synergies across activities

The knowledge and learnings gained from individual programs over the years can now be leveraged across NSB activities. Importantly, through all these years, we have learned that the best solutions are co-created with others.

Building capacity at the base of the pyramid

With the Novartis Malaria Initiative, we gained two decades of experience in fighting a devastating infectious disease in Africa. Working with intergovernmental organizations, nongovernmental organizations (NGOs) and funding partners, we pioneered an unconventional not-for-profit yet sustainable business model to maximize patient reach across public, donor-funded and private channels – expanding access for hard-to-reach patients. But a medicine is only as good as the system that delivers it. So we developed long-term engagement with the international malaria community and national malaria control programs in Africa, building healthcare capacity (from training health workers to monitor drug supplies in remote facilities to supporting the revision and uptake of national treatment guidelines and fighting counterfeit drugs) to better manage and control the disease. An important learning was

that the further down the social pyramid, the more capacity building is required to educate patients and help train healthcare professionals.

Through Healthy Family, we developed a unique model of community health education to empower rural patients to adopt disease prevention and health-seeking behaviors.

We are now starting to leverage this model across other NSB activities, as it has the potential to be scaled up (even independently from our company), and to provide solutions to address the shortage of community health workers and primary healthcare in general.

Using digital tools to improve access to care

Early on, we saw the potential of digital as an enabler to strengthen healthcare systems. In 2009, we spearheaded SMS for Life, a digital platform first used

to monitor stock levels of malaria medicines and later expanded to cover more diseases and functionalities, such as disease surveillance and training. We are now exploring how to leverage this digital "nucleus" across NSB in Pakistan and Myanmar. What we learned from SMS for Life is that even if a system performs well technically, insufficient ownership by local stakeholders and early integration within national healthcare systems can threaten its long-term relevance and sustainability at scale. Although SMS for Life was implemented across Tanzania, the program was discontinued after five years. Despite several years of performance at scale, the phone-based system was faced with growing competition from emerging smart phone-based solutions that allowed to track several products more conveniently. Further, there was a lack of coordination among partners and donors (who changed several times during scale-up), and among the different levels in the healthcare system.

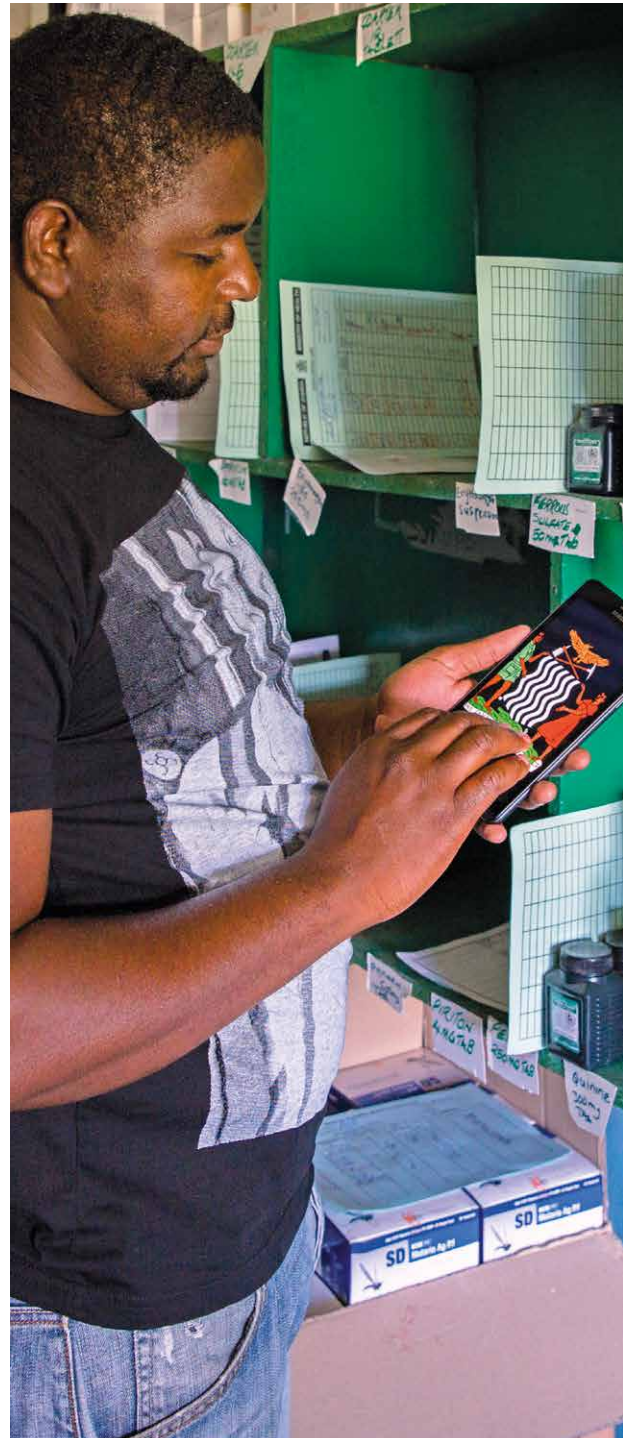
Especially in remote rural communities, digital technologies have proven extremely effective in helping us gain insights into access barriers for these populations.

Recent changes of the system transformed today's SMS for Life into a smart phone-based application that can address several health system challenges. Moving forward, we want to further explore the use of digital in strengthening the health ecosystem. For this, we will need to transform the way NSB approaches digital, moving toward a full integration of digital solutions into our business strategy.

Accelerating impact through measurement and evaluation (M&E)

Although programs such as the Novartis Malaria Initiative and Healthy Family have brought health education and services to places where these were previously nonexistent, it is still nearly impossible to measure their outcomes and their impact on people's health. The ability to measure social impacts requires a longer-time horizon and a focus on outcomes at patient or household level. This is a difficult task for a single company, so we worked with Boston University (BU) School of Public Health to build M&E into the core of Novartis Access. We are aiming to also apply output- and outcome-based measurement to other NSB activities. The framework developed by BU is now gaining recognition as an industry standard.

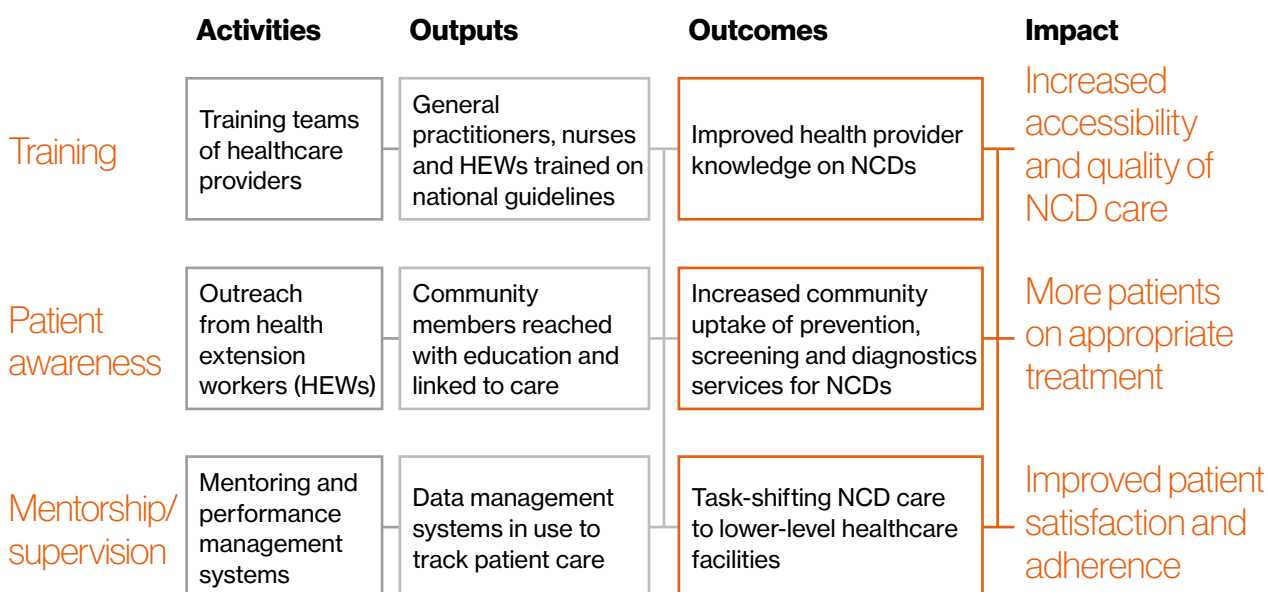
We are now applying this framework to steer our interventions. For instance, in Ethiopia, as part of our partnership with the Tropical Health and Education Trust (THET) to help decentralize noncommunicable disease (NCD) care in the country, we will implement the framework and measure our objectives against a set of output, outcome and impact indicators.



Securing additional support through catalytic funding

Catalytic funding is a key component of our capacity-building work, channeled specifically to projects that have an impact on healthcare providers and that support patients along the continuum of care. By aligning with local partners and governments early on, we can use catalytic funding to unlock additional support from key stakeholders in the form of co-financing, or government ownership.

THET measurement model



For instance, with Boehringer Ingelheim, we provided catalytic funding to the World Heart Federation (WHF) to train a cohort of 25 emerging leaders, primarily from low-income countries, to increase advocacy and policy work over the next three years on access to medicines for cardiovascular disease.

Further, in 2017 and 2018, we co-financed the Cameroon Baptist Convention (CBC) to implement their “Know your numbers” campaign, designed to increase awareness about NCD prevention and risk factors, and to screen and diagnose patients in communities. CBC funded part of the work, and the additional NSB support made it possible to engage with patients more deeply, improving one of the most challenging aspects of chronic disease management programs: patient follow-up.

We also consider catalytic funding when we invest in projects that do not have a large donor base since less than 2 percent of donor funding currently goes to NCD programs, despite the overwhelming disease burden. For example, NSB works with groups like THET to decentralize NCD education and care to community and primary care levels beyond hospitals. In the breast cancer space, we have started to collaborate with the world’s leading cancer organizations to support technical work to improve diagnosis and access to safe treatment in five African countries. We aim to apply learnings from what works

in high-income countries to low- and middle-income countries to help close the cancer survival gap.

Applying learnings from infectious diseases to address chronic conditions

Our experience with malaria has demonstrated that impactful interventions require an integrated disease management approach to ensure prompt diagnosis and treatment. A key learning from our work in the fight against the malaria epidemic was the need to have affordable treatments available in as many facilities as possible, so that patients do not have to travel a long way. The reality with chronic conditions may not be as acute, but testing people without providing them with care can have tragic consequences.

Over the years, healthcare systems have developed structures and approaches that the global health community now needs to build on to tackle infectious and chronic diseases in a comprehensive, effective way.

Ensuring distribution and supply chain integrity

Through our work on the ground, we know that medicines bought by countries at low prices sometimes end up with a 300-400% or even higher markup, leading to unaffordable prices for patients. Further, stock-outs of medicines are frequent, as these

countries often have weak distribution networks. The poorest pay the most, even in absolute terms. We have tried different approaches, together with partners, to help ensure we can deliver a reliable supply of quality medicines at affordable prices down into rural communities. One approach has been to collaborate with partners to minimize markups along the supply chain. We have also used digital tools to help manage medicine supplies and stocks to ensure treatments reach the right patients at an affordable price.

At the launch of Novartis Access in Kenya, we went one step further and worked with Management Sciences for Health (MSH) to identify risks that may be detrimental to product integrity (including product leakage), and subsequently informed health authorities.

Developing new financing solutions

The gap to fill to achieve the Sustainable Development Goals is estimated at more than USD 3 trillion, meaning that novel financing approaches are needed to combat infectious and chronic diseases. Also, we must move away from vertical “silo” financing for different diseases (HIV, tuberculosis, malaria, etc.) to a horizontal approach that has robust and accessible primary care for all illnesses at its core. All over the world, we are now seeing new approaches emerge. For example, the recent launch of a new malaria

financing initiative by the Asia Pacific Leaders Malaria Alliance with the Asian Development Bank (ADB) and the Global Fund could influence how we finance the fight against NCDs. For its part, NSB has been supporting the startup phase of the Defeat-NCD Partnership to create a matching funding mechanism whereby governments match or come close to matching a financial commitment made by a national private sector company or organization. We are also working on an impact investment fund in partnership with a social impact equity firm to improve access to quality healthcare for underserved populations. The aim is to offer equity to healthcare enterprises that are at a growth stage and are addressing critical needs.

Taking a more flexible approach

In the first year of Novartis Access, we realized that the portfolio approach, rather than a product-by-product approach, while commercially attractive, posed a set of implementation hurdles for procurement agencies, NGOs and government clinics. While it is important to maintain a commercial balance between cost and value, we have become more flexible regarding the portfolio composition to respond to country requirements. We are now proposing even more tailored solutions, including the entire Novartis product range registered locally, in the countries where NSB took over operational responsibility in January 2018.





Another case in point that illustrates our flexible approach is how we operate in Asian countries. If the public healthcare system can reach underserved patients, we collaborate with governments on Novartis Access. If the public healthcare system exists but needs strengthening, we engage in public-private partnerships with governments, academia and other providers to build capacity. If the public healthcare system cannot reach underserved patients, we work with other players in the private market and with NGOs to launch Healthy Family programs.

Expanding beyond the public sector

When launching Novartis Access, we decided to restrict supply of the products to the public or quasi-public sector. However, learnings from the ground – underlined by the results from the Boston University baseline study in Kenya – showed that in lower-income countries, although the majority of NCDs are diagnosed in the public sector, patients buy their medicines in the private, for-profit sector. This led NSB to expand distribution into the private sector when taking over operational responsibility for the entire Novartis offering in early 2018.

Creating sustainable business models

In 2001, Novartis signed a groundbreaking 10-year agreement with the World Health Organization (WHO) to supply its antimalarials at cost to the public sector in endemic countries. The expectation from the WHO was that Novartis would supply no more than 2.5 million treatments annually. Yet, over the past 15 years, more than 880 million treatments have been delivered to the public sector, exceeding the original forecast by a factor of more than 20. While this at-cost model proved effective in fighting an acute infection like malaria, we knew we could not apply it to Novartis Access. Because chronic illnesses require early detection and ongoing treatment, we need scalable ways to help ensure uninterrupted access to medicines. Donations and at-cost approaches are important but not sustainable, especially for chronic diseases. We need to create self-sustaining business models so that we can strengthen public healthcare systems for the long term without relying on donations. This is why with Novartis Access, we targeted a price that enables us to operate a social and sustainable business over time. Novartis can offer public sector buyers a price of USD 1 per treatment, per month, due to three elements: the anticipated scale of the program, the lean portfolio, and the significant off-patent component of the offering.

Changing the pharma model from the few to the many

Novartis Social Business (NSB) was launched in October 2016, bringing key access-to-medicine programs under one unit, including the Novartis Malaria Initiative, SMS for Life, Novartis Healthy Family, Novartis Access, as well as the work we do with major NGOs. The reason for combining these programs was that a patient-centric model (rather than therapeutic verticals) would best support healthcare systems that are stretched and under-resourced – as is typically the case in lower-income countries – to manage the dual burden of infectious and noncommunicable diseases.

An important step in this direction was taken in January 2018, when NSB assumed responsibility for the full Novartis portfolio in Malawi, Rwanda, Tanzania, Uganda, Laos and Cambodia. These countries were selected because they are large enough for social business models to scale up and be sustainable over time. We are now also leading the Sandoz business in Burundi, Kenya and India. For various reasons, such as a lack of healthcare infrastructure and substantial proportions of people living in poverty or in remote rural areas, novel business models are needed in these countries.

This decision was in line with the results of a baseline study we conducted with Boston University in 2016-2017 on the availability and affordability of Novartis Access treatments in Kenya. One key finding was that the majority of patients living in remote areas receive their diagnosis in public health facilities but buy their medicines in private ones, which are usually better stocked but more expensive. If we want to have a meaningful impact, we need to extend beyond the public sector and work with private distribution partners as well. However, this is not sufficient; we also need to find ways to ensure we reach the different population income segments with an adapted product and price offering.

Progress updates

We managed to grow the existing business in higher-income segments in **Cambodia, Laos, Rwanda** and **Uganda**, but experienced challenges in other East African countries.

In **Kenya** and **Uganda**, we expanded into the middle-income segment through the launch of a lower-priced pediatric formulation against childhood pneumonia. We expect to launch this pediatric formulation in **Tanzania** in the coming months.

In **Cambodia**, we started to work with a new distributor, introducing additional treatments and increasing product availability and affordability beyond major cities.

For lower-income patients, we are making good progress via Novartis Access, with more than 80% of the medicines in the portfolio granted marketing authorizations in **Kenya, Rwanda** and **Uganda**. In addition, as tenders play a significant role in the public sector, we are testing a new tender process and tracker in **Rwanda, Tanzania** and **Uganda** to optimize our participation in future tender offers.

Tiered pricing covering the entire income pyramid

In the countries under NSB responsibility, we are now exploring a new approach. Together with health authorities, we are currently tailoring our product portfolio to healthcare needs, with a view to launch in 2019 a tiered pricing (and packaging) strategy based on household wealth and specific distribution channels. This builds on the learnings from our baseline study, which explored the relationship between household wealth and access to NCD medicines in Kenya. We found new evidence that the poorest pay higher prices for their medicines, creating an undue financial burden on the most vulnerable households. In particular, our study revealed that the poorest patients pay the most for their acute asthma medicine.

Our goal is that, regardless of income, all patients in these countries will have full access to our range of products, across public and private channels, at prices they can afford. This is an important step toward universal health coverage. We will adapt this tiered-pricing model over time as we implement it in more countries.

Challenges on the horizon

NSB is based on volume strategies with low margins; a challenge is to make internal stakeholders understand that NSB is not a commercial threat to the broader organization and can complement their access strategies. Avoiding this tension will require aligned objectives between NSB and other parts of the Novartis business.

Further, we need to continue embedding a social business mindset into the growth plans of the company. This will be essential to generate lasting social impact in lower-income markets and for vulnerable populations overall.

A broader challenge is that there is no commonly accepted methodology to value and monetize societal returns, and to support investment decisions by

placing equal weight on social and financial impacts and returns. Part of the issue is that often financial returns solely guide investments, favoring a short-term rather than long-term perspective. Doing social good is still perceived as a soft notion (i.e., a “feel-good” factor), when in fact progress on social objectives should be measured against the same types of hard-core indicators used for financial and environmental objectives. Showing evidence that access programs drive tangible health improvements by moving from output (such as patient reach) to outcome measurement (such as the number of patients with controlled hypertension) will be key for progress.

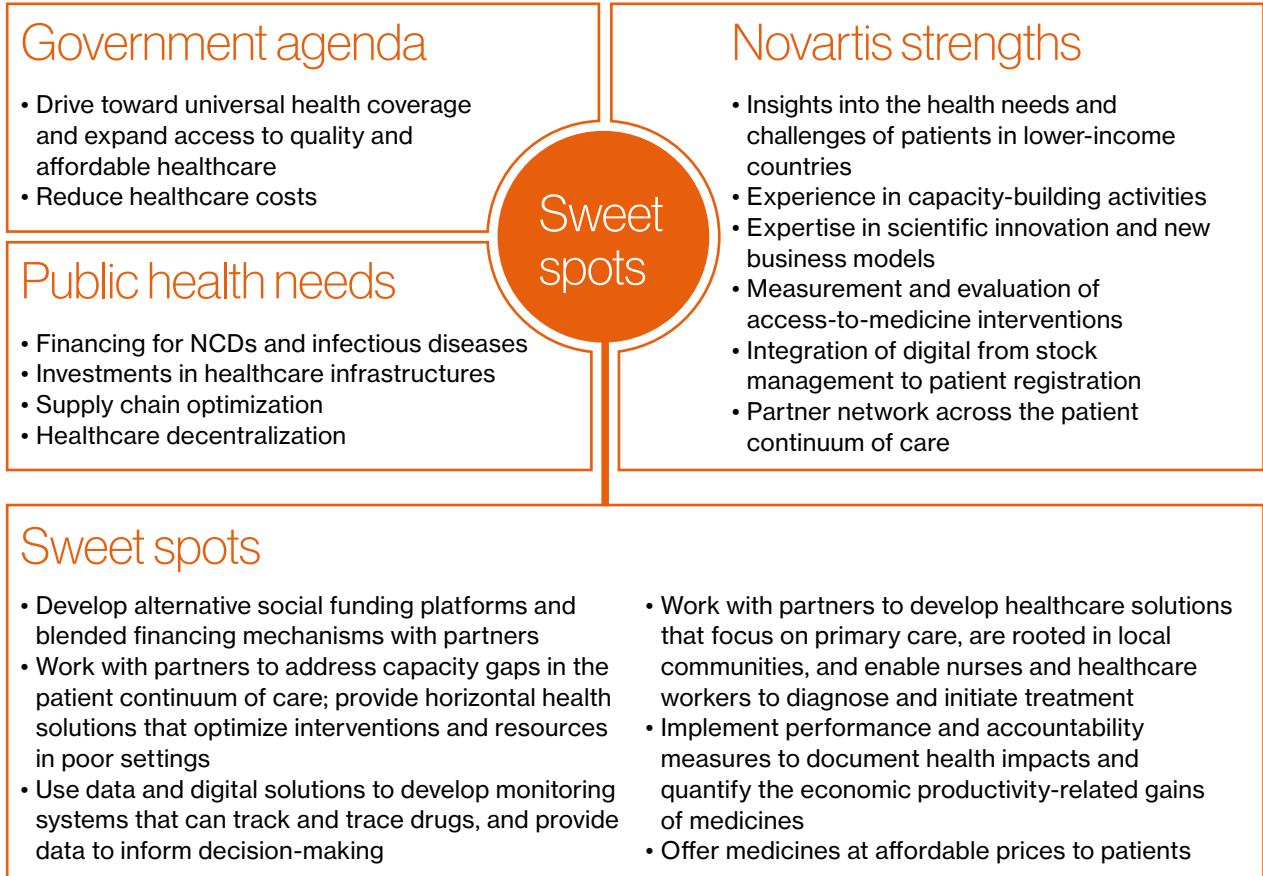
Opportunities moving forward

Despite the challenges, our ambition is to reach more than 50 million people by 2023 through tiered pricing, geographic expansion and digital technology. Scaling up self-sustaining business models creates several opportunities for Novartis:

- Our new market and tiered pricing strategy, coupled with the availability of our products in the public and private sectors, will enable us to demonstrate this strategy works for both Novartis and society, and to replicate and scale up these models in other geographies.
- Addressing NCDs in low- and middle-income countries requires a value chain approach. NSB has been providing catalytic funding to the Defeat-NCD Partnership, which aims to reduce the burden of diabetes and hypertension in least developed countries through knowledge and expertise sharing, technical assistance to build capacity, procurement and distribution of NCD products, and innovative financing mechanisms. We are exploring how to support the partnership also in the future.
- NSB has been leading the way on independent measurement and evaluation, setting standards for access-to-medicine interventions. Moving forward, there are opportunities to use the model in other areas and countries to refine our approach and apply it more broadly to other Novartis access-to-healthcare programs.



At NSB, our ambition is to leverage opportunities at the intersection of public health needs, government priorities and our own expertise.



2018 country achievements

Burkina Faso, Gabon, Gambia, Kenya, Mali, Mozambique, Thailand, Uganda, and Vietnam

KAF156 antimalarial trial centers are now operational in these countries, and we expect to activate four additional sites by mid-2019.

Uganda

First medicine shipments hit the ground in December. We also started capacity-building activities with the Uganda Heart Institute and with the Uganda Protestant Medical Bureau (UPMB) to provide NCD training to doctors, nurses and healthcare workers. Walimu, a local NGO, will also train public sector officials and the UPMB on the new NCD national treatment guidelines.

Colombia and El Salvador

In El Salvador, we signed an agreement with the municipality of Santa Tecla to make Novartis Access medicines available to vulnerable populations. We also signed a memorandum of understanding with the Colombian Red Cross to deliver the Novartis Access portfolio to vulnerable populations in the country, starting with Venezuelan refugees.

Ghana

We engaged in discussions with the government of Ghana and the Sickle Cell Foundation of Ghana to establish a comprehensive and replicable model to help increase access to sickle cell disease medicines and improve patient outcomes.

Nigeria

In September, we signed a distribution and capacity-building agreement with Society for Family Health to launch Novartis Access in six states before rolling out the program across the country. We plan to reach 5 million patients in this first phase.

Cameroon

In February, we signed an agreement with the government's procurement agency to also distribute Novartis Access medicines in public health facilities. This should allow us to reach an additional 300 000 chronic patients. Later, we signed a distribution agreement with the Catholic Health Service of Cameroon, the country's largest faith-based organization, which provides health services to more than 30% of the population.

- Countries with NSB activities
- 2018 NSB country highlights

Ethiopia

We entered into a partnership with THET to deliver training and capacity building to bring hypertension, diabetes and chronic respiratory disease services closer to communities. We have also trained 55 pharmacists and health workers from the Red Cross on supply chain and quality assurance.

Vietnam

Cùng Sống Khỏe (Healthy Family) product sales have grown by more than 50% and health education activities implemented with the Vietnam Cardiology Foundation have reached 10% more people compared to last year. We are currently expanding our activities to the country's central provinces.

Philippines

More than 50 health camps have been conducted with Allied World Healthcare (AWH). Further, the digital platform we have been working on with AWH now has more than 37 000 people profiled. We are currently setting up a pilot to see whether community-based insurance can be offered to these communities, and we are developing a streamlined supply chain model with a leading distributor in the region.

India

With information technology provider Tech Mahindra, the Arogya Parivar (Healthy Family) team piloted a digital platform with Aquarelle, a supplier to apparel company Levi's. Results showed that 16% of factory workers were diagnosed as anemic and subsequently treated. Further, a subgroup analysis showed that absenteeism was reduced by 4% on average in little less than one year. We also ran a pilot to include nutrition supplements in our product offering; unfortunately, we did not manage to bring distribution down to doorstep level in a sustainable manner.

Zanzibar

We joined forces with Vodacom Tanzania and the Ministry of Health of Zanzibar to implement SMS for Life in the country. The platform will be deployed to around 190 government-owned health facilities to report weekly medicine stock levels. In September, SMS for Life was awarded the Commonwealth Digital Health Award 2018 in the category emergency informatics.

Kenya

The first Novartis Access medicines are now available in public health facilities via the Kenya Medical Supplies Authority, and other drugs will be added in the coming months. Work is also progressing with MSH and Medtronic Labs to establish an end-to-end system for NCD management.

Rwanda

60% of the NSB portfolio is now available in the country and first Novartis Access treatments reached patients this year. In September, with the Ministry of Health and the Rwanda Medical Association, we trained about 200 doctors and initiated capacity-building activities to strengthen local NCD management. We will conduct similar activities through the Rwanda Biomedical Center.

Driving scientific innovation to address key healthcare needs

Novartis has a track record of addressing big healthcare challenges. Our decades-long experience in fighting malaria has taught us that to be effective, we need to be active on multiple fronts. We need to continuously invest in R&D for new medicines that can fight the next line of drug resistance; we need to develop improved medicines when therapeutic options are limited or nonexistent; and we need to make better use of existing prevention and treatment tools. We are now applying these learnings to sickle cell disease, another high-burden disease that takes a particular toll on children in lower-income countries.

Investing in science to create the tools that will help achieve malaria elimination

Although malaria case incidence has fallen globally since 2010, the rate of decline has stalled and even reversed in some regions since 2014. There is fear that progress could be hindered unless major changes happen in the funding and delivery of healthcare services.

This concern was highlighted by African opinion leaders participating in Malaria Futures for Africa

(MalaFA), a research study on progress and remaining challenges toward the WHO 2030 malaria elimination targets. The work was commissioned by Novartis and co-chaired by Dr. Richard Kamwi from Elimination 8 (E8) and professor Bob Snow from the KEMRI Wellcome Trust Research Program, Kenya, and the University of Oxford, United Kingdom.

Experts pointed to mounting evidence that malaria parasites are becoming resistant to current medicines – including artemisinin-based combination therapy (ACT), today's standard of care – and that mosquitoes





are becoming resistant to insecticides used to control them. Some said they fear that resistance will spread faster because of expanding trade and travel between Africa and Asia, where first signs of drug resistance are emerging. Others said it is just as likely that resistance will emerge independently in Africa. Yet respondents stressed the need to make better use of existing tools, including pediatric ACTs, until new medicines become available.

As we face emerging resistance, we need to forcefully invest in R&D for next-generation antimalarials. Against this background, on World Malaria Day, we announced a USD 100 million investment to advance research and development of next-generation antimalarial treatments over the next five years.

Throughout the year, we continued to make progress in malaria drug development. We presented the initial results of a cohort of 12 patients in our KAF156 trial exploring the safety and efficacy of the compound in combination with a solid dispersible formulation of lumefantrine. Belonging to a novel class of molecules, this compound has the potential to clear malaria infections – including resistant strains – and block parasite transmission. The data presented showed the combination was well tolerated, and all 12 patients were clear of the initial malaria infection by Day 4 and remained a parasitic until Day 29, the last day tested. KAF156 trial centers are now operational in seven African countries (Burkina Faso, Gabon, Gambia, Kenya, Mali, Mozambique and Uganda) and in two Asian countries (Thailand and Vietnam).

Novartis is leading the development with scientific and financial support from Medicines for Malaria Venture (in collaboration with the Bill & Melinda Gates Foundation).

Combating a disease that takes a high toll in Africa

Sickle cell disease (SCD) is a global health problem, with the highest burden of disease concentrated in sub-Saharan Africa; up to 50-90% of children born with the disease in Africa die before the age of 5. This is due to the high prevalence of the faulty gene on the continent, compounded by poor treatment capabilities and extremely limited newborn screening services. This means most children with SCD are not diagnosed early enough. We can see a clear disparity when comparing Africa to other parts of the world, where newborn screening for SCD is available and the condition is managed as a chronic disease.

Despite the adoption by the WHO of an SCD strategy for Africa in 2010, the disease is largely absent from the global agenda. This prompted Novartis to convene a SCD roundtable during the World Health Assembly in 2018, with representatives from national governments, academic institutions, professional associations, philanthropic organizations and industry.

Participants discussed successes and barriers for SCD interventions in sub-Saharan Africa, and ways to deliver sustainable impact for patients. Increasing government ownership and WHO involvement, linking

diagnosis with comprehensive SCD care services, and filling data gaps with research to improve patient outcomes were among the approaches advocated to achieve long-term gains.

Some African countries are taking important steps to fight the disease. Ghana, for instance, is setting up screening centers for newborns.

Throughout 2018, we engaged in discussions with the government of Ghana and the Sickle Cell Foundation of Ghana to help bring a sense of urgency to this deadly disease. Our goal is to work with local partners to establish a comprehensive and replicable model to improve access to SCD medicines and patient outcomes.

Given our long-term commitment to patients with hematologic diseases, we are hopeful we can help lower the toll of the disease in the future. With this objective in mind, Novartis Oncology has developed a monoclonal antibody to help prevent the painful crises of sickle cell disease, and is aiming to file this medicine globally in 2019. Furthermore, Sandoz submitted hydroxyurea, the only FDA- and EMA-approved drug for the treatment of SCD, for registration in Africa, starting with Ghana and Kenya in August 2018. We received approval in Ghana three months ahead of schedule, which will accelerate our efforts to bring the treatment to communities most affected. In addition, we have initiated the development of a pediatric formulation of hydroxyurea.

Developing treatments that are adapted for children

Children are not small adults, and they therefore require treatments that are adapted in terms of regimen, dose and formulation. In recent years, progress has been made in the development of pediatric formulations. Advances have enabled greater dose flexibility, easier administration,

and better acceptance by children. However, new pediatric formulations only address a small part of all therapeutic needs in children.

Further, despite a reduction in child mortality by more than half since 1990, infectious diseases, including serious bacterial infections such as pneumonia and sepsis, continue to take a significant toll on children.

Responding to the call from UNICEF to combat childhood pneumonia, we developed pediatric amoxicillin, today recommended by the WHO as a first-line treatment for childhood pneumonia. Over the last three years, we have supplied more than 3 million pediatric amoxicillin treatment courses to UNICEF and Médecins Sans Frontières.

Novartis is now also active in the fight against childhood pneumonia through the Every Breath Counts Coalition, a global network established in 2018. Coalition partners representing more than 30 organizations are working to help target and increase investments for pneumonia prevention, diagnosis and treatment, with the goal of ending preventable child pneumonia deaths by 2030. The coalition will start in the 10 countries with the largest numbers of children at highest risk of death. Expanding pneumococcal vaccine coverage will be a top priority along with increasing access to better diagnosis and treatment tools, including pulse oximetry and child-friendly amoxicillin.

In another effort to reduce child deaths from drug-resistant infections, we announced in September a partnership with the Global Antibiotic Research & Development Partnership to accelerate the development and availability of generic antibiotics. Development will target heat-stable pediatric formulations against bacterial infections – a leading cause of death in children under age 5 in low- and middle-income countries.



Embracing digital for better health and stronger healthcare systems

The ongoing digital revolution is expected to accelerate worldwide progress in healthcare in ways that were hard to imagine just years ago. By seizing the opportunities that the internet, mobile devices and other digital technologies provide, we can expand healthcare access, improve quality of care, and revolutionize health education at the community level.

A decade of digital experience in malaria

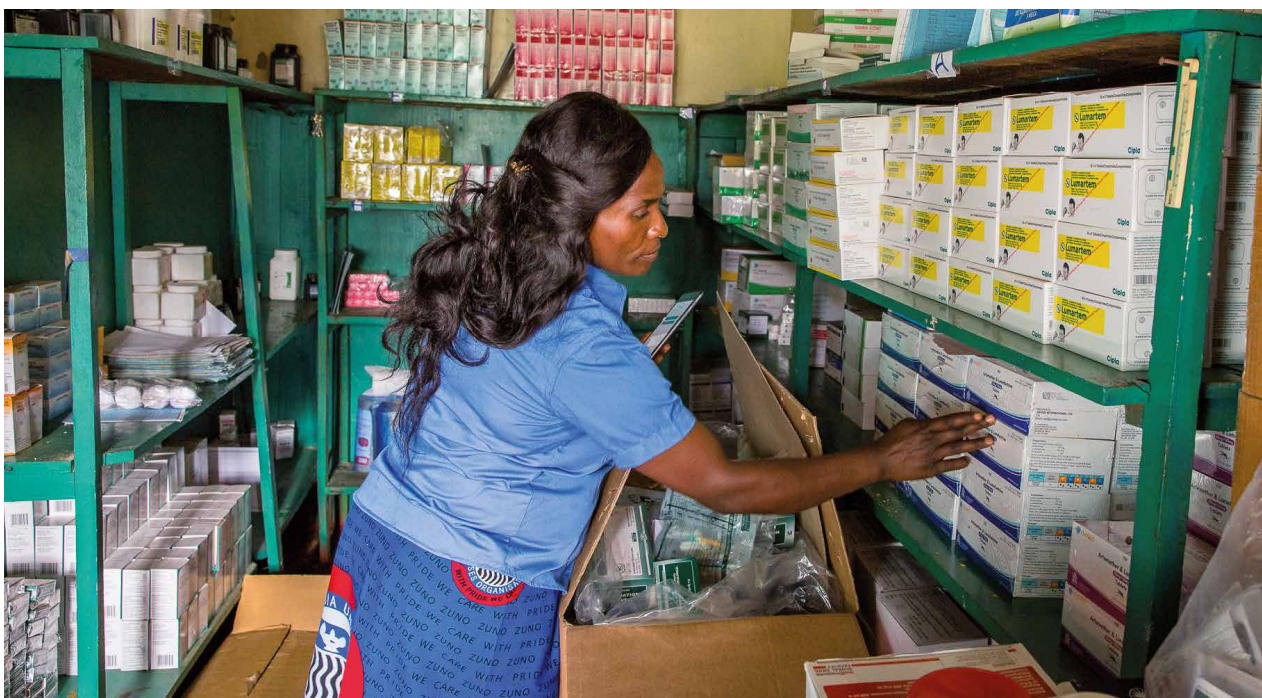
In 2009, Novartis broke new ground when it spearheaded SMS for Life in Tanzania, using a combination of mobile phones, SMS messages, the internet and electronic mapping technology to track weekly stocks of malaria medicines in remote health facilities. Since then, the program has expanded to six countries in sub-Saharan Africa and has grown to include more products and functionalities. For instance, the latest version of SMS for Life uses tablets to provide training to health workers, helping empower local practitioners.

In 2017, we supported the development of SMS for Life 2.0 in Kaduna State, Nigeria, and provided the necessary training. The solution was handed over to the Ministry of

Health and will be integrated into a broader digital health approach. Beyond health, the SMS for Life platform has also ignited digital activities in other areas, such as monitoring of school attendance in Kaduna State.

In Zambia, Nigeria and soon Zanzibar, the program is technically supported by Mezzanine, a subsidiary of Vodacom, and Novartis is providing funding together with other partners. The objective is to fully integrate SMS for Life into national healthcare systems and to enable full ownership by ministries of health in these countries.

Over the years, SMS for Life has won several prestigious awards and most recently the Commonwealth Digital Health Award 2018 in the emergency informatics category.



“Moving forward, it will be important for NSB digital health initiatives to continue maturing and growing with the rest of the ecosystem, as this will enhance ability to scale up and have impact. In particular, connecting the data collected with a country’s health information systems to make it interoperable with the national system and usable for data analytics will be essential.”

Florence Gaudry-Perkins, founder of DHP-Digital Health Partnerships

Tailoring digital solutions to country needs

Building on the SMS for Life experience in mHealth, we have expanded our digital activities to other NSB programs, including Novartis Access and Healthy Family. During our 10-year journey, we have taken a learning-by-doing approach, gathering insights and leveraging learnings. We have always considered the digital space as a laboratory where we can build on the knowledge gained to develop the next-generation solution and inspire others to join in the effort and contribute to the digital health ecosystem.

In the near future, our digital offering will include three elements: management of a patient database, monitoring of key disease parameters, and adverse drug event reporting. The solution will be adapted to country needs, and reports will be customizable, enabling the tracking of key health data such as stock reports, real-time data, alerts, patient and treatment monitoring, and geographic and demographic data.

For patients, the process will be simple: Following their visit to the doctor, they will register in the system to receive their treatment. Patient data will be verified using biometric information and/or fingerprints. As soon as a prescription is recorded, medicine stock levels will automatically be updated, enabling accurate stock management from the warehouse to dispensing pharmacies.

This solution is operational in Pakistan and will be deployed as soon as Novartis Access products hit the ground. The IT system developed with Greenmash registers patients, notifies them of their next appointment, tracks medicine dispensing (aiming to remove fraud by ensuring medicines reach patients included in the prime minister’s national health

insurance program), and provides essential information to monitor and manage medicine stocks. Reports, charts and maps will be automatically generated, providing aggregated, real-time information to support decision-making by the Ministry of Health.

Exploring the use of digital technology to deliver healthcare to remote communities

To address the dearth of qualified doctors in rural areas in India, the Arogya Parivar (Healthy Family) team set up a digital platform with information technology provider Tech Mahindra to connect patients to primary care specialists. Doctors provide online consultations and diagnose patients based on an initial screening done by a trained nurse, who is physically with the patient. In order to test if the system could work and if patients would be comfortable in video consultations, a pilot was conducted with Aquarelle, a supplier to apparel company Levi’s, in Jigani near Bangalore. Over a year, health camps were held with workers in one plant, on topics ranging from anemia, menstrual health and hygiene to diarrheal disease. We are currently in discussions with Levi’s on how to sustainably scale up the program.

In addition, in collaboration with another digital partner, the Arogya Parivar team is piloting a new awareness initiative to bring healthcare education to areas that are beyond its current coverage. We believe these interactions will help accelerate positive health-seeking behaviors in communities.

Over the next five years, we plan to expand Arogya Parivar into new states and make broader use of digital solutions to reach an expected 15 million people across India.

“Novartis was not afraid of supporting an initiative that would benefit all pharma players instead of just being known as the sponsor of SMS for Life. Interventions like SMS for Life are propelled by a vision of the future of last-mile supply chains instead of a more reactive approach that waits for public endorsement before making the commitment.”

John Vorster, CEO, Mezzanine

Co-creating solutions yields the greatest opportunities

In the digital health space, a key to success is for governments to integrate efforts across ministries and to coordinate when possible with external stakeholders in the private and nonprofit sectors. The greatest opportunities in digital health emerge when NGOs, business executives and government leaders all pull in the same direction.

This sort of collaboration is happening in the Philippines, where we are experimenting with a social business startup, Allied World Healthcare (AWH), to use technology and innovative collaborations to solve common barriers to access. Working with other partners (Microsoft, PwC, the National University of Singapore and Singtel), and using expertise and funding from Novartis, AWH has developed a digital platform called Curis.

Patients are invited to register on Curis during health camp sessions supported by health authorities and local community leaders. Curis creates a digital patient record based on self-reported data from patients. An algorithm flags potential health issues, and patients are then referred to a local healthcare practitioner who can address health concerns and add information to the patient record over time. The system also works offline, which is important in rural areas with weak internet connectivity.

The platform is now operational in one of the most populous districts of the Philippines, with 37 000 patients enrolled. Focus is on the so-called “semi-detached communities” that are a one- to three-hour drive from the nearest health facility, as this is where the highest opportunity for impact lies. This platform has provided insights into the health needs of these populations and the challenges they face in accessing healthcare. Further, the data helps inform local authorities on disease prevalence, leading to a better understanding of the community health

profile and of ways to improve healthcare services, such as by providing patient health education, medical appointment services, videoconference consultations, and new delivery methods for medicines. We are now setting up a pilot to see whether community-based insurance can be offered to these communities, and we are developing a streamlined supply chain model with a leading distributor in the region – both of which could foster deeper collaboration among partners to enhance the government’s comprehensive universal health coverage plan.

In Kenya, MSH, Medtronic Labs and NSB are working on an end-to-end system for NCD management, linking patients to community health workers, pharmacists and clinicians. We plan to start the program in three counties and expect to reach 50 000 patients in the next two years. Once registered on the platform, patients will be able to access blood pressure checks at community-based locations. Clinicians will be able to view patient data, provide feedback via SMS, and write electronic prescriptions – accessible through participating pharmacies.

Moving forward

The digital space is so vast that it is easy to engage in a wealth of activities, with little impact in the end. To help ensure we invest in the activities that best support our core programs (the Novartis Malaria Initiative, Novartis Access and Novartis Healthy Family) or broader healthcare system strengthening work, NSB developed a digital strategy in 2018.

A concrete first step is to align our digital interventions with the WHO’s recent classification of digital health interventions to harmonize activities in the field. Targeted primarily at public health audiences, this classification categorizes the ways in which digital and mobile technologies support healthcare system needs. As a start, we will focus on activities such as healthcare provider training, prescription and medication management, telemedicine and supply



chain management. This will entail consolidating our efforts and aggregating processes and tools in the area of NCDs, and redirecting capabilities to where short-term wins can be achieved. For instance, we are exploring the use of digital capabilities for our new sickle cell disease program in Ghana. Building on the existing newborn screening tool, we will explore options to expand capabilities to develop a patient registry and monitor the patient journey.

Although digital holds tremendous promise, it cannot alone fix every problem or address every health need. With this in mind, we believe we should focus on the following three priorities:

- First, outcomes. In many countries, health providers are rewarded for tasks they perform. Instead, healthcare systems should reward success based on health outcomes achieved, and treat digital

technology as a set of tools for achieving those outcomes and not just outputs.

- Second, we need to understand data. Digital enables us to capture and mine data for insights at every level – from individual biology to global patterns of disease. Training curricula for care providers and administrators should include instruction in statistics, data management and analysis that keeps pace with digital advances. Further, we also need to find better ways to turn data into timely and effective actions that address healthcare gaps.
- Third, we should recognize that digital is valuable to the extent that it improves how systems function. Physicians should not spend more time entering data than they do caring for patients. Digital can actually play a role here too, automatically processing data and freeing providers to do what they do best.

Partnering to solve healthcare ecosystem challenges

Capacity building is an important component of the Novartis Social Business strategy to reach patients in lower-income countries. Experience shows that capacity gaps in the patient continuum of care generate access barriers to affordable treatment. In the pursuit of partnerships to co-create solutions, we collaborate with like-minded partners that have expertise in working with low-income and vulnerable populations. All our capacity-building work includes measurement and evaluation so that we can document outputs, outcomes and impact – informing future areas for improvement.

Until now, our capacity-building approach was focused on partnerships with healthcare-related organizations. However, recognizing that a multitude of actors are involved in the patient continuum of care, we are now also starting to work with non-healthcare organizations that can lend technical expertise, and potentially also co-finance projects, to increase sustainability at scale.

We partner with organizations in four areas: community awareness and linkages to care, healthcare system strengthening, distribution and supply chain integrity, and advocacy and policy.

Community awareness and linkages to care

Our Healthy Family programs use innovative business models that build local, sustainable capabilities for healthcare – including access to healthcare,



education, infrastructure and distribution – for people living at the base of the pyramid in India, Kenya and Vietnam. Local health educators teach their communities about health-related issues, host health education meetings, and explain the importance of seeking out diagnosis and treatment from a qualified doctor before a condition worsens. Since 2010, more than 40 million people have been reached through health education in these three countries.

In 2018, Arogya Parivar in India reached more than 7 million people through health education activities. We work with more than 33 000 medical practitioners, 10% of whom provide voluntary support in medical camps to increase access to quality health services. We also run a mentorship program to enhance the medical knowledge of healthcare practitioners in rural areas, in particular on diagnosis and treatment for chronic conditions. In 2018, we trained 600 doctors on diabetes management.

In Kenya, Familia Nawiri social teams had more than 165 000 community interactions in 2018, bringing the total number to more than 900 000 interactions since launch. Health camps also continue to attract people, with 32 000 patients diagnosed and treated in 2018.

In Vietnam, NCDs are now causing four times more deaths than infectious diseases. Especially in rural areas, many people remain undiagnosed and are therefore unaware of their condition.

Cùng Sống Khỏe is supporting the Ministry of Health by increasing awareness of diseases and treatment options, and providing expertise on how to run health education meetings and health camps in communities. In 2018, we held 4 200 health education meetings and health camps in 14 provinces, reaching 210 000 people. Topics included basic health education on diabetes, hypertension, respiratory conditions and diarrhea.

We are partnering with the Cameroon Baptist Convention Health Services (CBCHS) to provide community health education and screening for the leading NCDs in seven health districts in Cameroon. More than 18 000 community members have been screened through their clinics and community-based outreach since launch in 2017, with a referral rate of close to 25%. Between the start and the end of the “Know Your Numbers” campaign, there has been an





increase of close to 80% in the uptake of screening services. CBCHS regularly adapts health provider trainings and programs to increase the ability to follow up with patients after screening and to ensure stronger linkages to diagnosis and treatment.

In Ethiopia, we have entered into a partnership with THET to deliver training and capacity building to bring hypertension, diabetes and chronic respiratory disease services closer to communities. Specifically, we plan to train and mentor healthcare professionals – ranging from doctors to nurses and health extension workers at hospital, health center and community levels – on diagnosis and treatment. In 2018, we supported the development of a train-the-trainer module to enable screening and diagnosis of patients with hypertension, diabetes and asthma. In December,

THET conducted a master training with the doctors responsible for regional trainings. We expect to screen 400 000 community members over two years in about 60 sites.

In the Philippines, we are engaging with NGOs, such as Allied World Healthcare, to organize health camps in rural areas, where villagers can visit a local doctor and are provided with health education. More than 50 camps were held in the Philippines in 2018.

Health system strengthening

Activities in this area focus on building capacity in local health services on screening, diagnosis, referral mechanisms and patient compliance, as these all contribute to increased access to medicines.



Importantly, the activities always align with a country's health strategy to help ensure government buy-in and long-term sustainability.

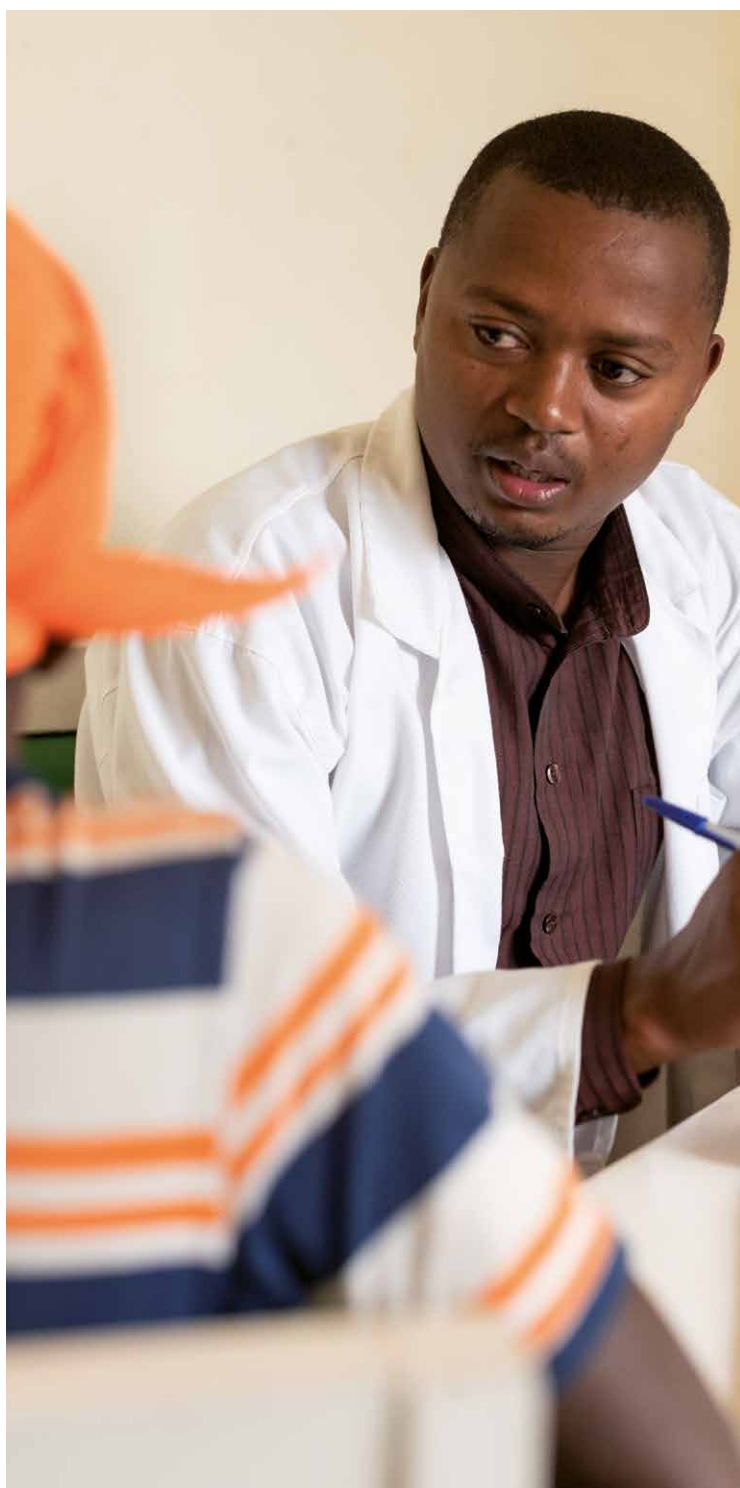
In Uganda, discussions with faith-based organizations and the private sector are well advanced. Discussions have also taken place with the Uganda Cancer Institute and the Uganda Heart Institute, two institutions that provide state-of-the-art care in specialized and modern centers. Novartis Access products will also be made available in these centers, leading to a significant reduction in out-of-pocket expenses for patients.

The American Cancer Society (ACS) completed pilot trainings for the ChemoSafe program in Ethiopia and Kenya this year. ACS will continue to conduct trainings

and disseminate tools that help improve quality of care in health facilities in Uganda and Rwanda. The American Society for Clinical Pathology (ASCP) has worked with laboratories across Ethiopia, Tanzania and Uganda to help procure and set up automated equipment. The group has also trained laboratory technicians on telemonitoring.

Together, ACS and ASCP trained more than 80 healthcare workers in diagnostic laboratories and facilities administering chemotherapy care in 2018. Year One learnings have revealed a need for a regional approach to ensure quality standards are aligned.

Duke-NUS Medical School has developed a modeling tool that creates NCD policy scenarios. We are exploring the use of such a tool with the Cambodian Ministry of



Health to enable evidenced-based decision-making as the country engages more deeply in its NCD strategy, including how to provide comprehensive care to fight these conditions. In 2019, Duke-NUS will lead training with Ministry of Health officials and analysts to build their capacity to manage this increasing disease burden.

In Vietnam, we continue to partner with the government on health education for patients and on training for rural doctors to enhance NCD management and strengthen primary care through our Cùng Sống Khỏe program. We plan to expand it in Vietnam's central region in 2019.

As part of the malaria commitment announced on World Malaria Day in 2018, we will work with partners to drive integrated community case management (iCCM) initiatives for children in Nigeria and the Democratic Republic of Congo in 2019, and in two more sub-Saharan African countries in 2020.

These countries bear the highest number of malaria-related child deaths. iCCM is recognized as a key strategy for increasing access to essential treatments and for reducing child mortality from treatable conditions such as malaria, pneumonia and diarrhea. In Nigeria and the Democratic Republic of Congo, we will also implement disease awareness campaigns and capacity-building activities for healthcare professionals.

There is currently a strong focus by the government of Kenya on universal health coverage, with four counties serving as pilots.

Through the Christian Health Association of Kenya and the Kenya Conference of Catholic Bishops, we continue to provide ongoing medical education on NCDs, in particular for newer molecules that have been recently included in the national treatment guidelines.

Over the last two years in Kenya, together with UNICEF, the Kenya Medical Training College (KMTCC) and the Ministry of Health, Novartis has tested a training curriculum on 70 community health extension workers, focused on child health and pneumonia. KMTCC adopted this curriculum in May and plans to roll it out to 10 of its major campuses. Further, together with World Friends, we trained 200 community health

volunteers responsible for creating awareness at the household level about various health topics, including child health and pneumonia.

We believe that creating awareness of respiratory illness and appropriate management guidelines is critical. This is why, in late 2017, we partnered with the Ministry of Health, UNICEF, the Clinton Health Access Initiative and other pharmaceutical companies to organize a symposium with stakeholders from 47 counties in Kenya. Together we updated and trained these stakeholders on the new guidelines for childhood pneumonia.

Distribution and supply chain integrity

Activities in this area focus on improving medicine distribution for low-income and hard-to-reach patients through designated channels, helping ensure products are in stock and stored in good condition in rural areas, and avoiding excessive price markups for patients. Activities are always aligned with national supply chain management capacity. We measure outcomes and conduct trainings based on local needs as appropriate.

In Pakistan, we have developed an IT system with Greenmash to register patients and track medicine dispensing. This will provide essential, anonymized data to enable accurate stock management from the warehouse to dispensing pharmacies, and help ensure the medicines reach the right patients. The system will be implemented in the country in 2019. We are also in discussions to replicate a similar platform in Myanmar.

Further, we are experimenting with a novel approach to help strengthen supply chain management and quality assurance on the ground through an employee volunteering program whereby Novartis experts train partner organizations. In 2018, train-the-trainer workshops were organized with about 100 people, including pharmacists, accountants and warehouse personnel at CBCHS in Cameroon and at the Ethiopian Red Cross Society.

Advocacy and policy

Advocacy and policy shaping at global, regional and national levels enable resource mobilization on the ground. Projects with actionable advocacy tap into

key decision-makers, provide a clear call to action, and offer tools or a roadmap that can support positive change, such as updating treatment guidelines or mobilizing resources for interventions.

We have supported the World Heart Federation in its work with 25 emerging leaders across the world to increase advocacy and policy work on access to medicines for cardiovascular disease. This cohort has completed a remote and in-person training curriculum. In addition, leaders have started pilot projects in South Africa and India. In Fiji, Mozambique and Nigeria, projects focused on assessing consistency between national treatment guidelines and essential medicines lists. We are also gauging the feasibility of applying innovations from community-based HIV care to hypertension care in these countries.

We commissioned the Malaria Futures for Africa (MalaFA) report in 2018 to understand the opinions of African leaders on progress toward global malaria goals. It was distributed at key malaria-related events, from the Malaria Summit and the Commonwealth Heads of Government Meeting to the Multilateral Initiative on Malaria conference and the Malaria World Congress. The overwhelming calls for more funding for operational research and for more domestic financing are the two issues that seem to raise particular interest among policymakers.

The president of Namibia presented the report to the Southern African Development Community ministers of health in November. Many of these global stakeholders have requested a further report focusing on Southeast Asia and India to inform policy in that region. This report is now underway.

We actively advocated bringing the health and finance agendas closer together under the next G20 presidency in 2019. In particular, we believe business can contribute to health investment through sustainable access models and innovative financing mechanisms. This requires robust measurement to assess impacts and define where investments could scale up such impacts.

Measurement and evaluation

Peter C. Rockers, assistant professor, Boston University School of Public Health, is part of the team that developed a methodology to evaluate the impact of Novartis Access in Kenya.

We asked him about the progress of this study.

What are the key takeaways from the Boston University baseline study in Kenya?

The baseline study produced several important findings.

We found tremendous geographic variation in diagnosed hypertension and diabetes in Kenya. In counties with a predominantly rural population, there appears to be a large amount of undiagnosed disease, and strategies to increase access to diagnostic services in these areas may be important. In the meantime, demand for NCD medicines in these areas is quite low, and Novartis Access could improve efficiency by explicitly targeting higher-prevalence counties.

We also found a strong wealth gradient in access to NCD medicines, with the poorest patients least likely to have the medicines they need. Furthermore, we found that among patients who had medicines, the poorest actually paid the most for them. This seems due in part to the poorest being located in "medicine deserts," where a lack of local competition leads to higher prices and where traveling to distant outlets where prices are lower is difficult. Novartis Access could have a substantial impact on equity by targeting remote communities with low-cost medicines.

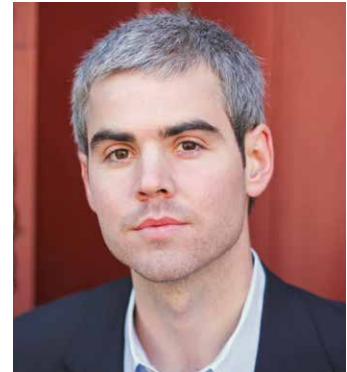
Additionally, we found that most NCD patients in Kenya purchase their medicines from private sector outlets. Prices at private outlets are on average higher than those at public and nonprofit outlets, but they seem to be more accessible for much of the population. It may be difficult for Novartis Access to control the final price of medicines distributed through the private sector, but offering medicines at private outlets may serve to reach a greater number of patients.

We are now midway through the study: What are the midline results? Can we see if Novartis Access is already having an impact?

A manuscript describing the results of the study is forthcoming in *The Lancet Global Health* and will be published early 2019. We look forward to discussing our findings with the global health community soon.

Are the midline results calling for any adjustments in Novartis Access?

In addition to generating evidence on program impact, the study has produced key process-related learnings that suggest a few potential adjustments to Novartis Access.



Peter C. Rockers
Assistant professor,
Boston University School of Public Health

First, NSB should consider distributing Novartis Access medicines through the private sector in Kenya and possibly in other countries where the program will be rolled out.

Second, as Novartis Access is rolled out in additional countries in the coming years, NSB should work with local government authorities to tailor the program and the medicine portfolio to each country's regulatory scheme, institutional capacities, treatment guidelines, disease burden and financial resources. Conducting a local needs assessment during the early planning phase of each new rollout is important for this process.

Third, the healthcare system in Kenya is not equipped to treat breast cancer at the primary care level. This may also be the case in other countries where Novartis Access will be rolled out. NSB should consider strategies focused on secondary and tertiary health facilities where breast cancer is often diagnosed and treated, to strengthen the impact of Novartis Access on access to medicines for breast cancer patients.

How will these results be used for Novartis Access and beyond our company?

The evaluation of Novartis Access in Kenya is, to my knowledge, the first to present experimental evidence on the impact of a pharmaceutical industry-led access-to-medicine program. It is our hope that the evidence generated by this study will inform the company's efforts to improve Novartis Access and other access programs going forward. The study also contributes to the public evidence base on strategies for improving access to medicines globally. The Novartis commitment to rigorous measurement and transparent reporting should serve as a standard for other industry efforts in this area.

Moving forward, how can the approach to measurement used in Kenya be simplified to more easily replicate it in other Novartis Access countries?

As part of the study in Kenya, we refined and validated a mobile phone-based method for data collection that relies on repeated surveying of a relatively small cohort of households and health facilities. Setting up the system requires an initial round of field work to enroll respondents and collect phone numbers, but is entirely phone-based thereafter. Ownership of mobile phones globally – even in very rural settings – has reached high levels in recent years and this presents an opportunity. Our method of phone-based surveying can be replicated in other Novartis Access countries to measure program impact at a relatively low cost.

Do you see an opportunity for other partners such as governments, NGOs or financial players to adapt the approach?

One key challenge that the global health community faces in addressing the growing NCD burden and achieving universal health coverage is a lack of infrastructure for measuring the state of medicine access in low- and middle-income countries. Without this infrastructure, it is very difficult to identify gaps and opportunities for policies and programs that aim to increase access. The phone-based surveying method that we have developed could be used to establish population-level surveillance systems to track indicators of access. The information produced by such a low-cost surveillance system could be made publicly available in near real-time for use by local governments, funders, patient and community groups as well as NGOs.

Novartis Malaria Initiative

In 2018, we reached a key milestone with more than 880 million antimalarials, including more than 370 million pediatric treatments, delivered without profit since 2001. If we include treatments sold in the private sector, the number exceeds 920 million treatments since 2001.

Our patient reach has steadily declined over the past five years, due to the increasing availability of WHO pre-qualified generic ACTs, eligible for international donor-funded procurement.

While we continue to make our ACT available, we are now also focusing on R&D for next-generation treatments and have committed to invest USD 100 million to accelerate the development of our new molecules.

| | 2018 | 2017 | 2016 |
|---------------------------------|------------|------------|------------|
| Patients reached ¹ * | 20 777 673 | 33 441 835 | 48 939 170 |
| Country presence ² | 18 | 32 | 30 |

¹ The malaria patient reach calculation was revised in order to harmonize the methodology across Novartis. We no longer consider a time lag between treatment shipment and patient reached. The calculation for malaria is now based on the treatments shipped in the respective calendar year.

² Does not include Belgium, France, Germany or the Netherlands, which are NGO hubs dispatching medicines to several malaria-endemic countries.

Novartis Access

Launched in 2015, Novartis Access offers a portfolio of medicines to address key NCDs. The portfolio is available to governments, NGOs and other public sector healthcare providers in lower-income countries at a price of USD 1 per treatment, per month. Beyond the portfolio, we offer capacity-building activities to support healthcare systems in preventing, diagnosing and treating chronic diseases.

To date, we have delivered more than 3 million monthly treatments to five countries,¹ and have signed agreements for 2019 implementation in Colombia, El Salvador, Pakistan and Nigeria.

| | 2018 | 2017 | 2016 |
|--|-----------|---------|--------|
| Number of submissions/approvals for Novartis Access products | 57/107 | 132/137 | 329/72 |
| Number of countries in which products are submitted | 27 | 24 | 21 |
| Monthly treatments delivered | 2 274 700 | 685 233 | 84 448 |
| Patients reached [*] | 1 542 865 | 386 463 | 8 470 |
| New countries where products are available | 2 | 1 | 2 |

¹ Cameroon, Ethiopia, Kenya, Rwanda and Uganda

* The patient number was calculated based on treatments delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (as NCD patients often take several drugs). Treatment adherence and treatment overlap are based on assumptions from developed markets.

Novartis Healthy Family

We just celebrated 10 years of Healthy Family programs. These innovative business models build local, sustainable capabilities for healthcare for poor populations in India, Kenya and Vietnam. Since 2010, programs in the three countries have reached more than 40 million people through health education; more than 3 million patients have been diagnosed and treated at health camps.

| | 2018 | 2017 | 2016 |
|--|-----------|-----------|-----------|
| Country presence | 3 | 3 | 3 |
| Number of health education meetings | 185 622 | 157 846 | 152 906 |
| People attending health education meetings | 7 804 604 | 7 689 921 | 7 717 849 |
| Number of health camps | 15 123 | 12 680 | 7 755 |
| People attending health camps | 720 795 | 579 620 | 428 793 |
| Number of health educators trained | 969 | 1 037 | 1 121 |




New businesses

Since January 2018, NSB has the responsibility for the entire Novartis product range in Malawi, Rwanda, Tanzania, Uganda, Laos and Cambodia. Ultimately, our objective is to implement a tiered pricing strategy to maximize patient reach across all income levels.

| | 2018 |
|--|---|
| Country presence | 6 ¹ |
| Number of submissions/approvals for NSB portfolio products | 13/4 |
| Key therapeutic areas addressed by NSB portfolio | Oncology, anti-infective, cardiovascular, respiratory, diabetes, women's health |
| Patients reached* | 697 771 |

¹ Nepal formally transitioned to NSB in January 2019. We are now also leading the Sandoz business in Burundi, Kenya and India.

Key performance indicators (KPIs)

| Novartis Social Business | 2018 | 2017 | 2016 |
|--|---|---|---|
| Countries with products on the ground ¹ |  |  |  |
| FTEs working for NSB ² | 651 | 555 | 535 |

Intervention strategies

| | | | | |
|---|--|-------------------|-------------------|-------------------|
| Community awareness | Awareness events | 185 756 | 157 846 | 152 906 |
| | Asia | 179 809 | 152 342 | 147 484 |
| | Africa | 5 947 | 5 504 | 5 422 |
| | People reached | 7 982 078 | 7 709 652 | 7 717 849 |
| | Asia | 7 628 098 | 7 521 705 | 7 562 266 |
| | Africa | 353 980 | 187 947 | 155 583 |
| Health service delivery | Points of service provision³ | 15 190 | 12 680 | 7 755 |
| | Asia | 15 050 | 12 568 | 7 677 |
| | Africa | 140 | 112 | 78 |
| | People reached | 765 055 | 585 821 | 428 793 |
| | Asia | 686 906 | 562 785 | 411 020 |
| | Africa | 78 149 | 23 036 | 17 773 |
| Health system strengthening | Health educators trained | 1 028 | 1 037 | 1 121 |
| | Asia | 1 018 | 1 027 | 1 111 |
| | Africa | 10 | 10 | 10 |
| | Healthcare providers trained | 697 | 311 | - |
| | Asia | 167 | - | - |
| | Africa | 530 | 311 | - |
| | Policymakers trained | 131 | 25 | - |
| Patients reached with products⁴ | | 24 832 581 | 35 202 276 | 50 048 631 |
| | Novartis Malaria Initiative ⁵ | 20 777 673 | 33 441 835 | 48 939 170 |
| | Novartis Healthy Family ⁶ | 753 493 | 941 860 | 883 990 |
| | Novartis Access | 1 542 865 | 386 463 | 8 470 |
| | NGO supply ⁷ | 1 060 779 | 432 118 | 217 001 |
| | New businesses | 697 771 | - | - |

1 Number of countries is decreasing due to the decline in sales of malaria treatments.

2 Full-time equivalent positions and contractors.

3 Points of service provision include facilities and health camps where healthcare services are provided.

4 The patient number was calculated based on treatments delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (as NCD patients often take several drugs). Treatment adherence and treatment overlap are based on assumptions from developed markets.

5 The malaria patient reach calculation was revised in order to harmonize the methodology across Novartis. We no longer consider a time lag between treatment shipment and patient reached. The calculation for malaria is now based on the treatments shipped in the respective calendar year.

6 Our patient reach declined in 2018 due to the divestment of one of our key products in the area of women's health.

7 We work with major NGOs (i.e., UNICEF, MSF, UNDP, ICRC and IDA Foundation) to enable access to affordable care for vulnerable populations.

Independent Assurance Report on the 2018 Novartis Social Business Report to the Board of Directors

Independent Assurance Report on the 2018 Novartis Social Business 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 Social Business Report of the company and its consolidated subsidiaries (Novartis Group).

Scope and subject matter

Our limited assurance engagement focused on selected indicators for the periods ending December 31, 2018, December 31, 2017 and December 31, 2016 as disclosed on page 34 in the Novartis Social Business Report:

- Number of countries with products on the ground
- Number of FTEs working for Novartis Social Business
- Total number of community awareness events and number of people reached
- Total number of points of health service provision and number of people reached
- Total number of health educators trained and number of healthcare providers trained and number of policy makers trained
- Patients reached within products

Criteria

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

Inherent limitations

The accuracy and completeness of the Novartis Social Business 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 Social Business indicators.

Novartis responsibilities

The Board of Directors of Novartis AG is responsible for both the subject matter and the criteria as well as for the selection, preparation and presentation of the information in accordance with the criteria. This responsibility includes the design, implementation and maintenance of the internal control system related 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 Social Business 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 Social Business 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, among others, 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 Social Business indicators concerning completeness, accuracy, adequacy and consistency
- Inspecting relevant documentation on a sample basis
- Reviewing and assessing the management reporting processes for Novartis Social Business 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



Stephen Johnson



Jennifer Kodat

Basel, 29 January 2019

