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We do not claim to have all the answers, but we ask the right questions and remain committed to learning from what works and what does not.

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Over the past decade, Dr Lutz Hegemann has helped transform Novartis' Global Health unit into a strategic pillar that bridges innovation with real-world access. Rather than focusing on visibility, the mandate centres on sustainable impact; embedding access into R&D, rethinking the value of established medicines, and advocating for systemic change in underserved regions. From regulatory harmonisation in Africa to decentralised care models in Southeast Asia, his approach reflects a blend of humility, operational depth, and long-term ambition.

How did Novartis' Global Health unit come into being, and what guiding principles underpin its work today?

I have led the Global Health unit at Novartis for the past ten years, during which time it has evolved into a strategically distinct unit, shaped by three core imperatives. The first was a recognition that certain disease areas, particularly malaria and neglected tropical diseases, fall outside the traditional commercial scope of the private sector, yet follow the same scientific and regulatory pathways. These conditions require a different metric of success, one that prioritises public health outcomes over financial return.

Secondly, we acknowledged that Africa warrants a differentiated approach. It is not a region where profit-driven models are always appropriate; rather, decisions must be guided by long-term,

impact-focused considerations. To reflect this, we separated Africa from our broader international operations and developed a dedicated strategy tailored to its unique needs.

Thirdly, the unit was built on the understanding that innovative business models are essential to expand access to underserved populations. This work does not replace our core commercial mandate but complements it, ensuring that we use our scientific capabilities in ways that deliver meaningful health impact. The evolution of Global Health at Novartis has been gradual, shaped by the realities of our pipeline, given that pharmaceutical development requires a decade or more of sustained focus before results are realised. Today, the unit serves as a platform to maximise our long-term contributions to global health through purposeful, pragmatic innovation.

In what ways is Novartis shifting its access strategy beyond traditional donation models, and how are governments responding to this evolution?

Access, in our view, must be an integral part of drug development, not a consideration introduced after regulatory approval. Since 2017, we have implemented a company-wide framework that embeds access planning into early R&D, typically from Phase II onward. This includes evaluating whether a medicine is fit for deployment in diverse health systems, ranging from those with advanced infrastructure to those with minimal resources. Factors such as thermal stability, affordability, and delivery mechanisms are addressed from the outset. Perhaps most critically, we consider whether local health systems are prepared to identify patients and deliver care effectively, something we can only influence through strong partnerships.

While the industry has historically relied on donation models to expand access, we recognise their limitations. Donations may offer short-term relief, but they are rarely sustainable. Our aim is not to generate profit in this space, but nor do we operate at a loss. We pursue a financially balanced model of what we call the “black zero,” where initiatives are self-sustaining and can continue delivering impact without perpetual external support. This discipline is essential if we are to maintain our presence in global health over the long term.

Collaboration is also fundamental to this model. We do not view global health as a space for competition between companies, but rather as one where complementary efforts across sectors can collectively address a broader set of needs, whether it be pharma, NGOs, philanthropy, or diagnostics for example. We focus on malaria, for example, while others concentrate on areas like HIV, reducing duplication and increasing overall reach. Encouragingly, we are now seeing a growing number of governments embracing ownership of their public health agendas rather than

relying solely on donor-driven solutions. That local commitment is indispensable; without it, even the most robust programmes are unlikely to succeed. Where governments are willing to lead, we have found the most effective and enduring partnerships.

How can Africa's healthcare model evolve to meet the demands of its demographic growth, and what role can regulatory harmonisation play in that transformation?

Africa's population trajectory is both remarkable and consequential; in the coming decades, the continent is expected to account for approximately one-quarter of the global population, with a particularly youthful demographic. This represents an enormous reservoir of potential, of talent, productivity, and social dynamism. However, the region's economic growth has not kept pace with its demographic expansion, and this disparity continues to constrain access to healthcare, innovation, and essential services.

One of the most pressing challenges lies in Africa's regulatory and trade fragmentation. With over 50 individual markets that each require separate approvals, packaging, and distribution pathways, it remains difficult to realise the economies of scale that the continent's population would otherwise enable. We have been closely involved in supporting the African Continental Free Trade Area (AfCFTA), led by H.E. Wamakele Mene, which seeks to address this fragmentation by harmonising trade frameworks, including within healthcare. Initially, health was not part of AfCFTA's mandate, but we were among those who advocated for its inclusion. That shift has now taken place, and broader industry voices, such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), are contributing to the process.

Complementing this is the work of the African Medicines Agency (AMA), a specialised agency of the African Union, akin to the Africa Centres for Disease Control and Prevention (Africa CDC). AMA aims to align regulatory standards and enhance oversight, and I see it as closely connected to the success of AfCFTA. The lack of regulatory cohesion is not merely bureaucratic, it has real consequences. At one point, we had a surplus of sickle cell medication in Ghana and an unmet need in Kenya, yet transporting that medicine directly between the two countries proved so prohibitively complex and costly that we had to reroute it through Switzerland. This is precisely the kind of inefficiency that harmonisation efforts are intended to resolve.

The appointment of Dr Delese Mimi Darko, formerly of Ghana's Food and Drugs Authority, as AMA's first Director-General is a particularly encouraging development. Her leadership brings deep regional knowledge and credibility to the role. If these frameworks continue to advance, I believe

we will see a more integrated, responsive, and sustainable healthcare environment in Africa, one capable of addressing today's challenges while positioning the continent for long-term resilience.

What are the main barriers to greater clinical trial inclusion in underserved regions, and how is Novartis contributing to more equitable research representation?

There remains a persistent disconnect between Africa's demographic weight which is home to roughly 20 percent of the global population, and its clinical trial participation which still accounts for only about one percent. The need to correct this imbalance is widely acknowledged, not only to ensure more representative data in terms of ethnicity and patient profiles, but also to reflect the diversity of healthcare delivery contexts across geographies. While the scientific rationale is clear, the path to implementation remains complex.

At Novartis, we have taken a collaborative approach to building the capabilities required to close this gap. Our work with the European & Developing Countries Clinical Trials Partnership (EDCTP), a longstanding EU-Africa initiative, and with the Gates Foundation, has focused on strengthening infrastructure for Phase II and III trials in infectious diseases. But infrastructure must be matched with consistent and meaningful use. It is not enough to train clinical teams if those skills are not applied; sustained trial activity is essential to ensure both operational relevance and long-term engagement.

A further challenge has been the fragmented nature of past efforts. For many years, different organisations have pursued overlapping capacity-building initiatives in parallel, creating confusion and inefficiencies. Encouragingly, this is beginning to shift. With the support of more structured platforms such as the Africa CDC, the European Union, and major philanthropic actors, we are seeing the emergence of stronger coordination and shared agendas.

In our own work, clinical trials in Africa are not simply a matter of responsibility, they are a necessity given the epidemiological focus of our portfolio. In countries such as the Democratic Republic of Congo, we collaborate with the Swiss Tropical and Public Health Institute (Swiss TPH), whose longstanding presence and expertise in malaria research offer a strong foundation. Through such partnerships, we are able to build on existing networks and capabilities rather than duplicating efforts.

This philosophy extends to other underserved regions. In Latin America, for example, we recently completed a significant clinical trial of Entresto (sacubitril/valsartan) for Chagas-related heart

failure. The study was conducted entirely in the region in partnership with the Brazilian Clinical Research Organization, an Academic Research Organization from Sao Paulo. This organisation not only brings deep regional understanding, but also helps ensure that research efforts are contextually grounded, locally owned, and globally relevant.

How is Novartis responding to the growing burden of non-communicable diseases in underserved regions, and what lessons can be drawn across different healthcare systems?

While classical tropical diseases continue to pose significant challenges in many low- and middle-income countries, the rise of non-communicable diseases (NCDs) such as cardiovascular conditions and cancer is reshaping the public health landscape. These diseases follow the same pathophysiology globally, yet health systems in many developing regions remain structurally unprepared to manage them. Addressing this emerging burden requires innovative delivery models tailored to system realities rather than scientific novelty.

Novartis has piloted such a model in Vietnam, combining its traditional pharmaceutical approach with a community-based care strategy that extends into rural areas and primary care settings. The goal is to identify and treat patients with cardiovascular disease early, before they require specialist care, through simple but effective interventions. This community health model not only complements the company’s innovative portfolio but also establishes structured patient journeys that improve access and long-term outcomes.

The model’s success has been recognised beyond the company. The World Bank, for instance, committed USD 10 million to help the Vietnamese government scale the initiative, a strong endorsement of its value and viability. Building on this momentum, Novartis has committed to expanding the programme to ten additional countries. The initiative is not framed as philanthropy, but as a self-sustaining, impact-driven business model designed to break even within three to five years, enabling long-term continuity without indefinite corporate support.

This approach also aligns closely with the World Health Organization’s call to strengthen primary healthcare globally. Reaching patients early and at scale cannot rely solely on hospital-based tertiary care, it requires decentralisation and stronger community infrastructure. Whether in high-income or low-income countries, primary care has re-emerged as a critical component of effective health systems.

Crucially, many of the access challenges seen in developing countries are mirrored in underserved populations across wealthier markets. In the United States, for example, increasing numbers of patients, and particularly the underinsured, face systemic barriers to care. From community pharmacists in the US to health workers in remote African settings, frontline providers are stepping in to bridge gaps traditionally managed by physicians. Though the settings differ, the structural role is often strikingly similar.

For Novartis, the question is not where patients are located, but whether they can access the care they need. The company is committed to identifying scalable, sustainable solutions that deliver meaningful value to patients across geographies, drawing insights from both mature and emerging markets and fostering a truly bidirectional exchange of healthcare innovation.

How do you see the nature of Novartis´s established medicines portfolio evolving over the next decade as more advanced therapies with demanding supply chains and higher prices will eventually come off patent?

At Novartis, we define established medicines as those that have moved beyond their initial launch phase. Meaning that, eventually, every therapeutic innovation, regardless of its complexity, becomes part of this portfolio. During my time leading this area, it became clear that even as platforms become more advanced, such as radioligand therapies with their unique supply chains and specialised distribution models, they will ultimately require integration into long-term portfolio strategies. The question is not whether this will happen, but how we, as an industry, manage the operational complexity of these evolving modalities over time.

Beyond the technical challenges, however, lies a more fundamental responsibility: ensuring that innovations continue to reach the patients who need them, even years after approval. Too many breakthrough therapies, despite their proven clinical value, remain inaccessible to large segments of the global population. When I led the Established Medicines unit, this was the issue that shaped my approach, recognising that a medicine’s relevance does not diminish with age, and that we must continue to invest in its reach.

Access should not be seen as a final-stage consideration. It must be embedded early in the lifecycle and sustained throughout. Once a product transitions internally, the mandate does not change, it must still be approached with the same urgency, creativity, and sense of purpose as during its development. The goal is not simply to manage legacy assets but to maximise the long-term societal value of innovation. That, to me, is the true measure of success in this space.

What role should the private sector, and Switzerland more broadly, play in strengthening health systems and ensuring sustainable impact in global health?

In today's shifting global health landscape, the private sector must go beyond transactional models of simply selling or donating medicines. Companies like Novartis, with a global workforce of 75,000 and deep local expertise, have the scale and responsibility to act as conveners, to bring together diverse stakeholders and co-create sustainable, systemic solutions. This requires rethinking traditional business models to prioritise inclusivity and long-term impact.

Our experience with sickle cell disease in Ghana illustrates this approach. When we began in 2019, the ecosystem for diagnosis and treatment was virtually nonexistent. We helped to lay the foundations for a comprehensive care pathway, including newborn screening, treatment, follow-up, advocacy, education, and destigmatisation. Collaborating with governments, diagnostic companies, and medical societies like the American Society of Hematology (ASH), we also took the unprecedented step of producing a generic version of hydroxyurea, a WHO-recommended first-line therapy, to support access in local clinics. While our direct role is limited, we aim to unlock broader partnerships and capabilities that create lasting change.

Switzerland is uniquely positioned to amplify these efforts. The country's dense ecosystem of academia, government, philanthropy, private enterprises, and international institutions provides a rare foundation for meaningful collaboration. As Professor Jürg Utzinger of Swiss TPH often notes, we sometimes underestimate the power of this proximity. Geneva hosts a critical mass of global health actors, from UN agencies to international NGOs, which enables Switzerland to be both a hub and a catalyst for action. Through partnerships with organisations such as the Medicines for Malaria Venture (MMV), the Drugs for Neglected Diseases initiative (DNDi) or The Global Fund to Fight AIDS, Tuberculosis and Malaria, we align our work with long-standing efforts to improve health systems, disease control, and supply chains in low- and middle-income countries.

This spirit of collaboration also extends to local initiatives. The canton of Basel-Stadt, for instance, has a longstanding twinning arrangement with Yopougon, a district of Abidjan in Côte d'Ivoire. Basel authorities recently funded a new health centre there, building on years of educational and cultural exchange. Swiss TPH and the Centre Suisse de Recherches Scientifiques en Côte d'Ivoire (CSRS) are now supporting this effort by contributing research capacity and workforce training. Novartis is also playing a role by integrating our sickle cell disease programme, aligning clinical intervention with local infrastructure and scientific input. This kind of tripartite cooperation

between government, academia, and industry demonstrates how collective investment can yield real impact.

Looking ahead, Switzerland has the potential to do even more. With strong institutional frameworks like the Swiss Agency for Development and Cooperation (SDC) in place, the focus should be on improving coordination and visibility. By aligning fragmented efforts and identifying synergies across sectors, we can move from isolated initiatives to a more integrated and effective global health strategy.

What final message would you like to share with your global peers on behalf of Novartis?

Our engagement in global health is rooted in decades of commitment, and while we do not claim to have all the answers, we remain constantly open to learning. As the world evolves, so must we. Understanding what has worked, where we have fallen short, and how we can adapt is essential to our progress.

Personally, I approach this work with genuine curiosity. I ask questions, I reflect, and I believe in being present. That is why I spend about a third of my time in countries across Africa, Latin America, and Asia; listening, learning, and seeing firsthand how our actions translate on the ground. That exposure shapes how we think and act as a company. What I would like to see, more broadly, is a deeper and more sustained commitment from the private sector to the cause of global health. This is not about improving how we are perceived or adding a line in a corporate report. It is about meaningful, lasting impact. That responsibility is one we must take seriously.

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