

Global Public Affairs

Novartis Position on Access to Medicines

At Novartis, we research, develop and commercialize medicines. Our breakthrough treatments and therapies have helped the lives of countless people around the world. However, billions more lack access to healthcare and medicines. Currently one third of the world's population does not have access to essential medicines, and with the global population projected to reach 9 billion by 2050, ensuring broad access is a critical issue.

Society largely relies on the pharmaceutical industry to develop and provide new medicines to address unmet medical needs, and there is increasing expectation around the industry's role in improving access to these medicines. At the same time, there is increasing stakeholder acknowledgement of the critical need to strengthen healthcare systems.

While the industry has a significant role to play, governments are primarily responsible for establishing functioning health care systems. The healthcare system is the fundamental tool to provide access to all facets of healthcare. Healthcare systems must ensure affordability for patients, sustainability for all stakeholders and adaptability to respond to new diseases, changing demographics, scientific discoveries and dynamic technologies.

Lack of access poses a significant barrier to long-term well-being and social and economic development around the world. It is linked to a host of interrelated problems – including poverty, under-funded and inefficient healthcare systems, limited healthcare infrastructure, lack of health education, shortage of trained healthcare workers, regulatory delays and high taxes on medicines – which further compound and perpetuate the issue. To improve access, we need a holistic approach that acknowledges the many complex factors contributing to the problem and relies on efficient stakeholder collaboration.

Key messages

- The healthcare system is the fundamental tool to provide access to all facets of healthcare, with governments having main responsibility for establishing functioning systems.
- Value-based healthcare is one of the solutions to delivering sustainable healthcare.
- We believe it is a shared responsibility of all healthcare stakeholders to help bridge the divide between those with access to critical healthcare innovations and those without. Novartis will play its part.
- Starting in 2018, for all our new medicines, we systematically integrate access strategies in how we research, develop and deliver medicines globally. This commitment is based on three key principles: needs-based R&D, affordability, and health systems strengthening.
- Development of and timely access to new medicines requires a strong innovation ecosystem. Mirroring our commitment, we ask governments and civil society to also contribute to improving access through addressing specific issues in the areas of R&D, affordability, and systems strengthening.

Novartis shares society's goal of better and more affordable healthcare for all. In order to achieve this, healthcare systems need to become more sustainable by focusing on delivering the most value to patients and society. Value-based healthcare is one of the solutions to deliver sustainable healthcare. In value-based healthcare, all stakeholders are incentivized to deliver the best possible outcomes for patients, healthcare systems and society. The reallocation of resources to those interventions that add the most value has the potential to improve the efficiency of health systems.

Novartis is contributing to society's shift to value-based healthcare by focusing our R&D efforts on unmet need and outcomes that matter. And we will consistently assess the value of our innovative medicines based on the value they deliver across three pillars: patient, healthcare system and societal value. We also work with partners to measure and improve patient outcomes in diseases where we have expertise.

Our commitment

We believe it is a shared responsibility of all healthcare stakeholders to help bridge the divide between those with access to critical healthcare innovations and those without. Starting in 2018, for all our new medicines, we systematically integrate access strategies in how we research, develop and deliver globally. This commitment is based on three key principles:

Needs-based R&D: We systematically assess our R&D portfolio against the unmet needs of underserved populations and integrate these needs, as appropriate, into our drug discovery and development strategy. For example, our current research efforts focus on reducing the burden of infectious and tropical diseases, including malaria, Chagas, sleeping sickness, leishmaniasis.

In addition to our extensive in-house R&D, we accelerate medical innovation through collaboration, with academic and industry alliances. We nurture a broad pipeline of innovative medicines across many disease areas.

Intellectual property (IP) is essential for investment in the R&D that leads to new medicines and also promotes access to medicines. Patent protection accelerates new product launches in higher- and lower-income countries alike, resulting in greater treatment options for patients. Novartis does not file or enforce patents in Least-developed countries (LDCs) or in Low-income countries (LICs). We will grant non-exclusive licenses to qualified third parties to supply our patented products exclusively to LDCs and LICs. See Novartis Position on Intellectual Property.

Affordability: We will price our new medicines based on the value they deliver to patients, healthcare systems and society. In addition, we will work to make our medicines available by considering effective affordability strategies (e.g., shared contribution models, patient assistance programs, social business models) and innovative solutions for disease management, as well as off-patent solutions to complement our leading innovative medicines portfolio. Our strategies will strive to take into account income levels, local affordability barriers and economic realities, while maintaining the sustainability of our business. We have led the development of social business models for more than a decade.

Healthcare systems strengthening: We will seek opportunities to lower local barriers to healthcare delivery, working in collaboration with governments and other partners to support quality patient care in areas where we can have the greatest impact. Together with our partners, we are working to empower patients to better understand and manage their disease, train and support healthcare workers and increase local research and clinical trial capabilities.

How our partners can help

Novartis seeks to work with all stakeholders to improve access to medicines for patients. Development of and timely access to new medicines requires a strong innovation ecosystem. We have identified a number of

contributions needed from governments and civil society to improve access:

R&D:

- Acknowledge the contribution IP protections make to development of and access to medicines;
- Prevent compulsory IP transfers;
- Promote specific incentives for challenges related to R&D for neglected diseases.

Affordability:

- Enable use of value-based, tiered, and innovative pricing models. Models must have mutually beneficial clinical and economic outcomes for healthcare systems, patients, and Novartis;
- Provide shared accountability for and sustainability of access to medicines by ensuring sufficient funding of health systems;
- Integrate cross-sectoral and donor efforts to leverage the dollar spend most efficiently for public health and develop new financing mechanisms, particularly for noncommunicable diseases;
- Limit mark-ups and taxes that increase the price of medicines along the distribution chain.

Healthcare System Strengthening:

- Enact and implement stable and predictable regulations and timely science-based regulatory and marketing approvals;
- Adopt sound principles for health technology and value assessments;
- Obtain political commitment to ensure sufficient financing of healthcare systems;
- Support innovative ways of delivering care to those in need;
- Optimize inefficient procurement and distribution systems that result in frequent stock-outs of medicines and devices throughout the healthcare system;
- Modernize storage facilities and conditions that currently cause significant waste of pharmaceutical supplies, unnecessarily driving up healthcare costs significantly;
- Provide training/capacity building for healthcare professionals/healthcare workers.

Through leveraging the collective abilities, strengths, and resources of all stakeholders to address these issues, we can make progress on this global challenge.

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