Novartis Position on Access to Healthcare

Introduction

Limited access to healthcare poses a significant barrier to long-term social and economic development around the world. Currently, one-third of the world’s population does not have access to essential medicines. In addition, with the global population projected to reach 9 billion by 2050 and with most of this growth in developing countries, ensuring broad access to medicine and healthcare is a critical issue.

Affordability is only one of the many hurdles to access to healthcare. Poverty, lack of access and poor health are inextricably linked, and poor patients are often faced with an inability to pay for medicines, sometimes even for the cheapest medicines. A lack of basic health education, limited investment in healthcare infrastructure, insufficient numbers of trained personnel and long distances from communities to hospitals or treatment centers are other significant barriers.

Effectively addressing this multi-faceted issue requires the collaboration and combined efforts of governments, healthcare professionals, healthcare companies and nongovernmental organizations (NGOs), with governments having the primary responsibility for improving public health and fulfilling the right to the highest attainable standard of physical and mental health, a core human right.

As a leading science-based healthcare company, Novartis has a responsibility to use its expertise and skills to address the needs of underserved populations. We believe our primary contribution to expanding access to medicines derives from our core business – to discover and develop medicines – and from the very essence of our mission – to improve and extend people’s lives. We believe this should apply to everyone, everywhere.

Our position on access to medicine and healthcare

Expanding access to medicine is a longstanding commitment of Novartis, and we challenge ourselves to intensify our efforts, to learn continuously and to adapt alongside our partners so that, together, we can meet this commitment.

We believe health outcomes can be improved for patients everywhere if more people are trained to prevent, diagnose and treat disease and if the right medicines get to more people.

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1 World Medicines Situation, World Health Organization, 2011
• New business approaches are needed to increase the affordability and availability of innovative and generic medicines in a sustainable way and at scale. There is no "one-size-fits-all" approach to access to medicine.
• Continuous innovation is fundamental in terms of research and adaptive development, as well as in terms of evidence-based delivery models. Innovative research leads to products that can address today's unmet medical needs and become tomorrow's off-patent generic and biosimilar medicines. A key enabler for investment in R&D to drive medical innovation is a strong intellectual property protection system.
• More needs to be done to strengthen healthcare services on the ground. More healthcare workers are needed who can prevent, diagnose and treat disease.

Our strategic approach to expanding access to medicine

We take a systematic approach to access to medicine, placing it at the core of our business strategy. Our focus lies in two areas within our control: product affordability (by increasing the affordability of our products through sustainable access strategies) and innovation (by embedding where relevant the needs of lower-income countries in the Development process). We also strive to integrate access strategies in our product launch plans in order to help patients in low- and middle-income countries benefit from our novel best-in-class therapies as early as possible. While we believe in the value of a strong intellectual property protection system, we do not enforce patents in least developed countries (LDCs).

We have set targets in the following areas:

1. **Control and eliminate diseases:** Contribute to efforts to control and eliminate diseases, including leprosy and malaria
2. **Pioneer new business approaches and healthcare delivery models:** Advance social ventures to tackle health problems of underserved, low-income patients in both the developed and developing world
3. **Find new treatments:** Continue to focus on neglected disease research, while expanding adaptive research that targets unmet needs of patients in developing countries

Sandoz, our generics division and the world's second-largest maker of generic medicines, plays an important role in our strategy to make medicines affordable and expand our portfolio in developing countries. We offer more than 1,000 high-quality generic medicines across a range of therapeutic areas. Newly registered products include treatments for communicable diseases as well as noncommunicable diseases (NCDs) such as diabetes and heart disease, which are a growing concern in emerging markets.

Our access-to-medicine strategy aligns with Business for Social Responsibility's Guiding Principles on Access to Healthcare,² which Novartis and other companies signed in 2013. Our activities and targets, as well as the number of patients we reach, can be found in our Corporate Responsibility Performance Report.

Our strategic framework for access to medicine

In 2015, the Novartis Access to Medicine Committee (ATM Committee) approved a new cross-divisional Access Strategy Framework which defines our pricing and access approach depending on income segments. The ATM Committee, chaired by the CEO, assesses opportunities to expand access to Novartis medicines, especially in underserved communities, and sets and monitors targets related to access.

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Recognizing that we need to be flexible in our approach in order to respond to various needs, the framework offers a set of tools to expand access to innovative and generic medicines.

**Differential pricing** is one such tool to adapt prices to the purchasing power of payors and patients (inter- or intra-country) while considering the sustainability of our business in higher-income markets as a key driver of continued innovation. In addition, we use tools such as managed entry agreements and shared contribution based patient assistance programs.

Novartis also partners with healthcare system payors on programs to increase access, including price-volume agreements, outcome guarantees and disease management programs that combine innovative medicines and generic pharmaceuticals. Programs that favor broader solutions that go "beyond the pill" can help drive improved outcomes. Yet, these approaches can only be successful if there is a shared accountability between pharmaceutical companies and healthcare systems.

At the lower end of the pyramid, differential pricing strategies are complemented by donations, non-profit initiatives and social venture programs.

We have developed indicators, including affordability measures and patient reach targets, to track the implementation of the Access Strategy Framework.

Affordability is a pre-requisite for access to medicine, yet by no means is it sufficient. Further, affordability is impacted by factors outside of our control such as mark-ups, taxes, tariffs, etc. This is why we work with our distribution partners to ensure the price patients pay for our products is kept to a minimum. Other collaborative initiatives around healthcare infrastructure and patient education are needed.

**Our approach to research and development**

Novartis sets its research priorities at the intersection of unmet medical need and strong science. Only later do we consider commercial opportunity. This focus leads us to actively target diseases where we can make a difference. Our "science without borders" approach to research recognizes and embraces the needs of increasingly global and diverse patient populations, including those with rare or neglected diseases, and seeks to address some of the key public health challenges, such as noncommunicable diseases and antimicrobial resistance. In 2016, Novartis joined forces with more than 80 international pharmaceutical and biotechnology companies to call for a global, united front with governments against the emergence of drug-resistant infections.3

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3 Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance, January 2016:
The Novartis Institutes for BioMedical Research (NIBR) and Novartis Pharmaceuticals Development focus on discovering and developing new therapies, including medicines to treat and prevent infectious diseases that disproportionately affect patients in developing countries, such as respiratory viruses and viruses that threaten patients with HIV/AIDS. The Novartis Institute for Tropical Diseases (NITD) in Singapore is dedicated to finding new medicines for neglected diseases, such as dengue fever, Human African Trypanosomiasis, malaria, and others.

We also undertake adaptive development by, for example, modifying existing medicines to increase treatment adherence or improve drug stability to better meet the needs of underserved and vulnerable patient groups like children and the elderly, and those living in high-heat and tropical climates. Sandoz is one of the few companies developing products specifically for children to treat diseases like pneumonia and tuberculosis.

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