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## The Novartis Declaration for Patients – What Patients Can Expect

### Introduction

We are inspired by patients.

This inspiration motivates us to revolutionize the research, development and manufacturing of innovative, high-quality medicines that help people live longer, with a better quality of life, giving more time to do the things that matter to them.

To do our best for patients we do not accept the status quo. We work to enable patient access worldwide so that patients and society can benefit as quickly as possible.

The depth and strength of our pipeline enables us to change the practice of medicine and to bring more breakthroughs with real benefits to patients and society. Our broad portfolio of products helps us to expand overall access to medicines, both through targeted patient access programs and widespread availability of affordable, high-quality generics and biosimilars.

We partner with people and organizations around the world because by working together we can make a greater difference.

We continually challenge ourselves to the highest standards of compliance, integrity and performance in all that we do to ensure a sustainable future of innovation for patients, society and Novartis.

As patients are our focus, it is important that they know what to expect from Novartis and that we are very clear about our commitment to patients and our role and responsibilities in key areas of interest, including:

- Access to our Innovative Medicines
- Patient Safety
- Respecting the Patient Perspective
- Data Transparency and Data Integrity
- Clinical Trial Input

### Access to our Innovative Medicines

Novartis conducts one of the world's largest clinical trial programs covering many disease areas.

We commit to registering our new treatments in every country that has participated in the clinical trials and to making the treatments commercially available wherever feasible.

Where a medicine is not commercially available, we will provide it (as permitted by local legislation) to those patients who participated in the clinical trial to ensure their treatment is not interrupted. In these cases Novartis works closely with the trial investigators, and in the context of existing local legal and regulatory frameworks, to extend access to the study treatment.

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We will actively demonstrate to physicians, governments and payers the value our products bring to patients and do our best to ensure that patients in need can access our products as soon as possible. We will work together with local governments and payers to find local solutions to get the right treatment to the right patient at the right time as quickly as possible.

We offer a variety of patient access solutions depending on need and where permitted by law and the country regulatory authorities, including:

- **Early Access Programs** – enables a treatment to be available to patients before it is approved for use on the market and officially launched
- **Expanded Access Programs** – enables a treatment under investigation to be available to patients for treatment outside an ongoing clinical trial
- **Compassionate Use Programs** – enables a treatment to be available to patients who have no treatment options, either because the current available therapies do not work for them or because they have exhausted all of their options, and cannot enter a clinical trial

We have assistance available to patients in countries such as the United States and Canada that includes help with co-payments.

When necessary we offer donation programs and work with payers on access programs that reflect the specific needs and the economic status of the countries.

We will price our products to support investment in continued research of future breakthrough patient therapies and the value they offer to society and patients.

### **Patient Safety**

Novartis is committed to making quality products that are safe and effective to meet patient needs and demands.

We will report adverse events to authorities in compliance with legislation.

Novartis is also committed to taking action against counterfeits and sub-standard medicines to ensure patients receive the right treatment they need.

### **Respecting the Patient Perspective**

We will listen to the important information patients and patient communities share with us on what it is like to live with their condition.

We believe in the active participation of patients and concerned citizens to improve healthcare services and outcomes for patients. We respect the independence and integrity of patient organizations. We partner with patient organizations around the world in compliance with local laws and regulations on projects of mutual interest and benefit, including disease awareness and education, better understanding the patient journey specific to each disease area, and activity in social media. We support patient activity through social media channels.

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We support ongoing patient advisory boards and roundtables in various disease areas where patient group representatives from around the world meet to discuss matters of importance to them.

We commit to ensuring that our products are packaged in a patient-friendly, easy-to-understand and use format and, where permitted by law, with labelling that recognizes the needs of patients to better understand what they are taking, including details about dosage, potential side effects, instructions on usage, etc.

## **Data Transparency and Data Integrity for Innovative Medicines**

### ***Data Transparency***

We recognize that patients need to trust products from Novartis and may want to access information on their own regarding these products.

In 2005, Novartis began the process of voluntarily disclosing summaries of Clinical Study Reports (CSRs) of its innovative medicines, while protecting patient privacy, on its own website (<http://www.novctrd.com>).

Novartis is committed to posting results of all interventional studies in patients and to providing full access to all blinded data from clinical trials upon request from academics and clinicians and after review by independent external experts.

In addition, the company will continue to publish detailed summary reports of clinical trial results of innovative medicines, both positive and negative, including trial design, key efficacy and safety data, and patient-friendly, easy-to-understand summaries.

### ***Data Integrity***

Clinical research conducted by independent investigators, with its focus on unmet medical needs, is an important part of drug discovery and development.

In July 2014, Novartis announced new global guidelines for Investigator Initiated Trials (IITs). The new guidelines reinforce our support for clinical research adhering to the principles of ethics, governance and transparency. The guidelines are clear that interactions between Novartis and scientific investigators are to be restricted to scientific issues only and that any financial support is for purely scientific activities without commercial involvement. With these guidelines patients can have confidence in the data generated by these studies.

### **Clinical Trial Input**

Novartis recognizes that patient knowledge and experience with their disease is valuable in the design of clinical trial protocols and outcomes. We are committed to inviting patient input early on regarding our clinical protocols design and desired outcomes as well as improving the way we share information with patients along the clinical trial process so that the patient perspective is truly represented in our clinical development programs.