Novartis 2017 US Transparency and Patient Access Report





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2017 highlights

23000

Full-time equivalent employees in the US, of which 6 800 are employed at our US-based R&D sites

\$3.4 bn

Invested in R&D in the US, representing 38% of our global R&D spend that totals \$9 billion 6

FDA breakthrough therapy designations received by Novartis in 2017

90%

Of our payments to healthcare professionals are related to R&D

770000

Patients received support through our copay assistance program in 2017 291000

Patients received free medication valued at over \$4.3 billion through the Novartis Patient Assistance Foundation Inc. over the past five years



Thomas Kendris

Foreword

At Novartis, we reimagine medicine to improve and extend people's lives. We have evolved as an organization over hundreds of years to always be on the leading edge of understanding and impacting human health. The medicines we deliver can help patients live longer and in better health, and provide significant benefits to our society and economy. As we look ahead, we once again must fundamentally evolve the way we work in order to continue to deliver on our purpose.

The world is changing fast, raising new challenges. Aging populations and the rise of chronic illnesses are straining healthcare systems. As people live longer, there is increasing emphasis on maintaining quality of life into old age, rather than on extending life by a few months. Meanwhile, our industry has lost much good will as society's expectations of healthcare companies have changed and increased. Trust is low and our contribution to society is under scrutiny.

At this critical time in the US, companies like ours need to transform our approach – challenging the status quo to strengthen innovation, providing greater transparency about our business practices and seeking new ways make our healthcare system more sustainable over the long-term.

The pharmaceutical industry cannot by itself address the issue of rising healthcare costs, but we at Novartis stand ready to partner with stakeholders across the entire system to understand how to deliver the most value to patients.

We support a shift to a system where medicines are priced based on the benefits they deliver in four areas: clinical, patient, health system and societal outcomes. We believe such value-based pricing can help improve quality and reduce waste in the healthcare system. We also believe it is more transparent and focuses everyone on what matters most – better outcomes for patients.

We are committed to working even harder to rebuild trust and return more to society. This includes finding new ways to expand access to our medicines and pricing our products responsibly. One way we're doing this is by establishing a set of Access Principles which we believe will help ensure a more consistent approach to access programs across products and countries.

We know our stakeholders have important questions about our business practices and our approach to tackling the challenges facing today's healthcare system, and hope the information in this report will help answer those questions.

We welcome your feedback:

→ <u>uscorporate.communications@novartis.com</u>

Sincerely,

Thomas Kendris

President, Novartis Corporation, and US Country and Legal Head

Science and innovation

Novartis discovers new ways to improve and extend people's lives. We harness the power of science to address some of society's most challenging healthcare issues. We develop breakthrough treatments and deliver them to as many people as possible.

Our medicines can have a dramatic impact on patients' lives. They can help people live longer and remain healthier, and they can provide significant benefits to our society and economy.

For more than 10 years, Novartis has been among the world's top 20 in research and development (R&D) spenders across all industries. Novartis invests more than 18% of its global revenue in R&D. In 2017, our R&D investments reached \$9 billion, exceeding our operating income (\$8.6 billion). In the US, we invested \$3.4 billion in R&D, representing 38% of our total global R&D spend.

In 2017, Novartis received six FDA breakthrough therapy designations.

Our pipeline, with more than 200 projects in clinical development, is consistently rated as one of the most respected in the industry. In 2017, Novartis received six breakthrough therapy designations from the US Food and Drug Administration (FDA). Breakthrough designation allows the FDA to expedite the development and review of drugs that are intended to treat a serious condition if preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy.

Our R&D efforts build on more than a century of innovation in medical science. For instance, 35 years ago we introduced the first immunosuppressant – a calcineurin inhibitor called cyclosporine – that made transplantation a reality.

In 2001, we introduced *Gleevec*, a life-changing medicine that has helped transform Philadelphia chromosome-positive chronic myeloid leukemia (CML) from a once fatal condition into a manageable disease. Today, nine out of 10 CML patients have a near normal lifespan.

With the introduction of *Entresto*, our medicine for chronic heart failure, patients now have the first and only treatment to significantly reduce the rate of cardiovascular deaths and heart failure hospitalizations versus the ACE inhibitor enalapril.

Most recently, the FDA approved *Kymriah* (tisagenlecleucel, formerly CTL019) to treat children and young adults with a deadly cancer called acute lymphoblastic leukemia. Novartis is the first company to receive approval for this type of novel immunocellular therapy, which reprograms a patient's own T-cells cells to fight cancer.

Our collaborative approach to science

New R&D technologies are being developed in a variety of places, from university labs and biotech startups to multinational companies. Novartis is constantly seeking the best technological advances and partnerships. We currently work with an external network of more than 300 academic and 100 industry alliances. We believe scientific collaborations can boost efficiency and accelerate progress by facilitating access to ideas, capabilities and talent. By joining forces with external innovators to pursue shared scientific interests, we can increase the breadth and depth of the science that we cover.

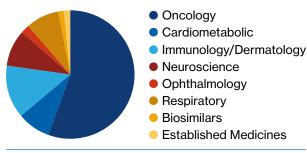
Novartis generally seeks collaborations at the stage of idea generation and early discovery through clinical proof-of-concept. We then invest in scaling up and completing the full development process, as well as in building the necessary manufacturing capacity. For example, we were the first major pharmaceutical company to advance an innovative new type of personalized cell therapy to fight cancer, known as CAR-T, through our collaboration with the University of Pennsylvania. Novartis has since invested substantially in clinical trials to demonstrate the therapy's safety and effectiveness to health regulators, as well as in a facility that is able to prepare the treatment for each individual patient.

Developing safe and effective treatments

Clinical trials are research studies intended to answer scientific questions and find better ways to treat or prevent diseases. They are fundamental to the development of medicines and devices.

Novartis conducts clinical trials globally for a range of diseases. In the US, as of December 2017, we had more than 142 pivotal trials¹ across disease areas.

Novartis pivotal trials per disease area in the US



Providing managed access programs for patients with limited treatment options

There are instances where a patient has a serious or life-threatening disease or condition for which all currently available treatment options have been exhausted and enrollment into a clinical trial is not possible. Novartis Managed Access addresses this need by making certain investigational or unapproved treatments available to eligible patients.

In the US, we currently have 23 managed access programs across disease areas.

Sharing clinical trial results

Novartis supports clinical trial data transparency. We believe providing access to information on clinical trials and their results serves study participants, researchers, patients and their healthcare providers, as well as the public at large.

Participants in clinical trials can gain access to new investigational therapies not yet available to the public, while helping advance medical innovation.

In 1999, Novartis began registering its clinical trials on <u>www.clinicaltrials.gov</u>, the public US clinical trial registry. We have registered more than 3 300 trials on the site since.

In 2005, before it became a legal requirement, Novartis was one of the first healthcare companies to publicly disclose clinical trial results from Phase IIb – IV¹ patient trials for our approved and unapproved innovative medicines on our website. Since then, Novartis now has more than 2 600 clinical trials available on www.novartisclinicaltrials.com.

In 2009, public disclosure of clinical trial results was later expanded to include all Phase I and Phase IIa¹ patient trial results for approved and unapproved innovative medicines on www.novartisclinicaltrials.com.

The results of Novartis clinical trials are also posted on other online public databases (US, EU and German results websites), and significant results are published in peer-reviewed journals. In 2014, Novartis began providing access to anonymized data to qualified external researchers via www.clinicalstudydatarequest.com.

In 2016, Novartis committed to help inform patients about Phase I and IIa¹ clinical trials they participated in by providing an easy-to-understand clinical trial summary. We expanded our commitment in 2017 to include Phase IIb and III¹ trials. All patient summaries will be posted on the Novartis website:

www.novartisclinicaltrials.com.

For more information:

→ www.novartis.com/our-work/ research-development

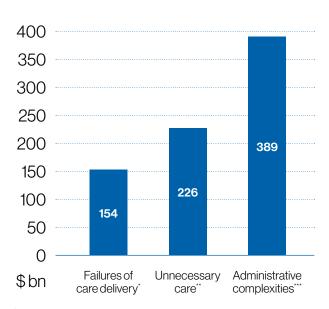
¹Clinical trials generally proceed through the following phases: In Phase I, researchers test a new drug in 20 to 100 healthy volunteers or people with the disease to gather information on safety and dosage. In Phase II, the drug is tested in several hundred patients with the disease to assess efficacy and side effects. Phase III studies, also known as pivotal studies, involve 300-3 000 or more patients with the disease and aim to demonstrate efficacy and monitor for adverse reactions. Phase IV trials are usually done after product launch to further explore safety and efficacy in several thousand patients.

Value and pricing

Driving the shift to value-based healthcare

In the US, it is estimated that 21% to 34% of health spending is wasted every year (i.e., between \$558 billion and \$910 billion).¹ To make healthcare affordable, wasteful spending within the system needs to be urgently addressed. We believe a value-based healthcare system could help reduce some of the unnecessary spending and focus everyone on what matters most – better outcomes for patients.

Estimated wasteful spending on healthcare in the US¹



- Failures of care delivery, such as lack of widespread adoption of known best care processes, cost the system up to \$154 billion.
- "Subjecting patients to unnecessary care, such as overuse of antibiotics or surgeries where alternatives exist, causes waste of up to \$226 billion.
- "Another estimated \$389 billion is lost due to administrative complexities, e.g., when limited physician time is spent on needlessly complex billing procedures.

Novartis is committed to taking a leading role in helping the healthcare system transform the current "pay-for-service" approach to one that ties payment to outcomes delivered.

We believe medicines and healthcare services (e.g., diagnostic procedures, medical consultations and drug prescriptions) should be priced and paid for based on the outcomes they generate, namely:

- Clinical outcomes, such as shrinking a tumor, reducing blood sugar levels or prolonging survival
- Patient outcomes, such as improved quality of life
- Health system outcomes, such as reducing the rate or duration of hospitalizations or the intensity of care
- Societal outcomes, such as allowing patients or caregivers to return to work

In the pharmaceutical sector, Novartis is pioneering the shift to value-based pricing. We aim to focus our pricing approach on the value our medicines deliver with respect to clinical, patient, health system and societal outcomes. We also apply US-specific cost- effectiveness modeling to inform US prices and embed patient- and payer-relevant endpoints in our clinical trial programs.

When measured on the outcomes they deliver, innovative medicines can play a critical role in helping reduce waste in the system. For example, when used appropriately, *Entresto* could save more than 28 000 lives per year in the US alone, and over a two-year period it could save more than \$27 million from reduced heart failure hospitalizations for every 100 000 patients treated.^{2,3} In the largest study ever conducted in heart failure patients with reduced ejection fraction (PARADIGM-HF), *Entresto* was shown to reduce cardiovascular deaths and heart failure hospitalizations by 20%, and all-cause mortality by 16%.

Additionally, *Kymriah* is the first FDA-approved CAR-T therapy and has demonstrated remissions in children and young adults with relapsed or refractory B-cell ALL. It offers the potential for sustained remissions

¹Berwick DM, Hackbarth AD. Eliminating Waste in US Health Care. Journal of the American Medical Association. 2012 Apr 11:307(14):1513-1516

² Fonarow GC, Hernandez AF, Solomon SD, et al. Potential Mortality Reduction with Optimal Implementation of Angiotensin Receptor Neprilysin Inhibitor Therapy in Heart Failure. JAMA Cardiol. 2016;1(6):1-4. doi:10.1001/jamacardio.2016.1724

³ Gaziano TA, Fonarow GC, et al. Cost-Effectiveness Analysis of Sacubitril/Valsartan versus Enalapril in Heart Failure Patients with Reduced Ejection Fraction in the United States. JAMA Cardiol. 2016; cardiology.jamanetwork.com/journal.aspx

for children and young adults at high risk of death who have few remaining treatment options. More specifically, *Kymriah* provides: 83% overall remission rate at 3 months. With median duration of response not yet reached in our clinical trials.

Kymriah is also the first therapy based on gene transfer to be approved by the FDA, and was approved under the FDA's Breakthrough Therapy designation and Priority Review programs based on the Novartissponsored, pivotal Phase II ELIANA study.

Our approach to pharmaceutical pricing in the US

- We believe in value-based pricing for our products and advocate for a healthcare system that supports this approach and enables patients to have access to the medicines they need
- We will manage price adjustments responsibly for our brand medicines as well as our biosimilars and generic products
- We will strive to ensure patient affordability for our products

Value-based contracting

Novartis is one of the first companies to start entering into value-based contracting for our medicines. We are still at the early stages of this approach and are learning from our experience. We have multiple agreements in place where payments are linked to the outcomes our medicines deliver.

For example, we have value-based contracts in place for our innovative heart failure medicine, *Entresto*, where cost offsets from prevented hospitalizations determine part of the payment to insurers; for *Tasigna*, where some payments have been tied to our ability to halt disease progression in first-line patients with a form of chronic myeloid leukemia; and for *Gilenya*, where in some cases payments are based on our ability to decrease the annual relapse rate for relapsing-remitting multiple sclerosis patients.

On August 30, 2017, the US Food and Drug Administration (FDA) approved *Kymriah™* (tisagenlecleucel) suspension for intravenous infusion for patients up to 25 years of age diagnosed with B-cell precursor acute lymphoblastic leukemia refractory or in second or later relapse. This was an exciting breakthrough that marked the first-ever approval of CAR-T therapy in the United States.

Novartis has developed a novel Outcome-Based Contract (OBC) for the approved indication and has begun executing agreements within the network of certified *Kymriah* Treatment Centers. Under the agreement, Novartis does not charge participating treatment centers for the cost of *Kymriah* when a patient does not achieve a response within one month following infusion.¹

However, even though many stakeholders agree with a value-based approach to pricing and contracting, the current US system includes many technical and regulatory barriers and is not yet set up to fully support this shift. For example, patients that use medications as stated in the product label may experience benefits that are not captured in the label. These benefits are of interest to the payers, providers and patients. However, due to current regulations, these benefits cannot be considered when developing value-based contracts. Removing such barriers and shaping the system is a long-term endeavor that will require concerted efforts and cooperation from all stakeholders in the healthcare system.

^{1.} The OBC is between Novartis and participating treatment centers

[•] Participation by certified treatment centers is voluntary

[•] The OBC applies to patients covered by all forms of insurance, including Commercial, Medicaid, Medicare, and other government health plans

Managing price adjustments responsibly

Novartis is committed to managing price adjustments responsibly for all of our innovative and generic medicines. In the past few years, our annual price adjustments have gradually decreased.

US product portfolio¹ – % change vs. prior year²

2013 2014 2015 2016 2017

Total gross price change ³	9.8%	9.9%	9.3%	6.2%	5.4%
Total net price change ⁴	7.0%	5.3%	1.3%	-2.0%	-2.1%

¹US product portfolio for 2013 to 2017 includes all medicines sold by the US Innovative Medicines Division, including Alcon Ophthalmics products, and all generic medicines sold by the US Sandoz Division.

In 2017, the gross price increase across our portfolio was 5.4%. However, our net price over the same period decreased by 2.1%. Gross price (also called list price or wholesale acquisition cost) is the starting price set by the pharmaceutical company. Net price reflects the final amount received by the company. The difference between gross and net price is largely the result of many negotiations that take place between the pharmaceutical company and other stakeholders in the supply chain – such as government payers, insurers, pharmacy benefit managers, wholesalers, retailers and hospitals – that typically result in discounts and rebates to the gross price.

These discounts and rebates are not necessarily passed on to the patient, meaning net prices may differ from the final costs absorbed by payers and patients. Further, stakeholders in the supply chain may apply additional charges, increasing drug prices above the discounted amount charged by the manufacturer.

2013 2014 2015 2016 2017

¹ Total US rebates, discounts and deductions calculated as a percentage of total gross sales

In the US, the total annual rebates and discounts on Novartis products (both innovative medicines and Sandoz generics) increased from 39.8% in 2013 to 49.5% in 2017.

Novartis publishes key financial information annually in its Form 20-F and Annual Report, including total rebates, research and development costs, and gross and net sales.

Key corporate publications:

→ www.novartis.com/news/publications

² The company's calculation of gross and net price changes was verified under agreed-upon procedures between Novartis and PricewaterhouseCoopers AG performed in accordance with International Standard on Related Services 4400. Our methodology may differ from the methodologies used by other companies. This pricing information should not be read in conjunction with the company's filings with the Securities and Exchange Commission.

³ Represents the year-over-year change in the average list price of Innovative Medicines brands, combined with the year-overyear change in the average wholesale acquisition cost (WAC) of the Sandoz products that had an increase in gross price in the period. Individual gross price changes by brand or product are weighted by current year gross sales.

⁴ Represents the year-over-year change in the average net price. The net price is the total gross price less total rebates, discounts and deductions.

² The company's calculation of the total rebates and discounts was verified under agreed-upon procedures between Novartis and PricewaterhouseCoopers AG performed in accordance with International Standard on Related Services 4400.

Patient access

Making our medicines accessible and affordable

Novartis works to develop new ways to deliver its medicines to as many people as possible. Globally, we offer an array of approaches, including patient access programs, patient assistance programs and product donations. Our generics division, Sandoz, also helps make affordable, high-quality medicines available to more people.

In the US, we offer access-to-medicine programs that aim to make sure that patients' out-of-pocket costs are not a barrier to access. We work with stakeholders such as insurers and governments, with the goal of ensuring no patient is left behind.

In 2017, we established a set of Access Principles that clarify our approach to access. These will go into effect in 2018. At their core is a commitment to integrate patient access strategies into all of new medicines launches. These strategies will be based on three key principles: systematically assessing our research and development portfolio against the unmet needs of underserved populations, further improving the affordability of our medicines, and systematically assessing our efforts to strengthen local healthcare systems.

Commercially insured patients

Currently, for US patients with commercial insurance, we offer copay assistance programs so eligible patients pay no more than \$30 for a 30-day prescription (i.e., \$1 per day) through retail or mail order for the vast majority of our branded and biosimilar products. This includes our cancer portfolio. As of January 2018, all our branded products without generic alternatives and our biosimilar products are available under these programs, subject to any limits imposed by a patient's individual health plan, pharmacy benefits manager or employer, and where allowed by law.

In 2017, Novartis copay assistance programs provided assistance to nearly 770 000 patients.

Government-insured patients

Due to current regulations, we are unable to offer copay assistance to patients covered by government healthcare programs (e.g., Medicare and Medicaid). While Medicaid patients already have the benefit of low out-of-pocket costs for their medicines, we believe regulations should be changed so that Medicare beneficiaries can also be provided the financial assistance available to commercially insured patients to help reduce their out-of-pocket costs for medicines.

Assisting patients with out-of-pocket costs can help reduce the level of unfilled or abandoned prescriptions and support their ability to adhere to their medicines as prescribed. This could ultimately impact longer-term health outcomes and reduce overall costs for the US healthcare system.

Uninsured and underinsured patients

Through the Novartis Patient Assistance Foundation Inc., we are providing medicines at no cost to eligible US patients experiencing financial hardship who have limited or no prescription drug coverage. We have increased the income eligibility limits for all branded products. For example, individual patients earning less than \$75 000 per year and families of four with an income below \$150 000 per year may be eligible for the program. We will continue to adjust income eligibility limits in accordance with changes to the federal poverty level and other external factors.

In 2017, the Novartis Patient Assistance Foundation Inc. provided more than \$1.4 billion in free medicines to more than 55 000 patients in the US. Over the past five years, free medication valued at roughly \$4.3 billion has been provided to around 291 000 patients.

Patient support services

Getting access to medications can be difficult, confusing, and at times stressful for patients. Novartis offers tools and support designed to help make that process easier. We offer a range of services to support patients with all aspects of access, from insurance verification to financial assistance to a supportive call center.

Find out more about our programs: Novartis patient assistance programs

- → <u>www.patientassistancenow.com</u>
- www.pharma.us.novartis.com/our-products/ patient-assistance

Novartis Oncology Universal Co-Pay Program

→ <u>www.copay.novartisoncology.com</u>

Today's innovative medicines are tomorrow's generics and biosimilars

Novartis is a global leader in the generics sector through our Sandoz Division, which offers biosimilars and high-quality generic medicines.

Novartis launched the first biosimilar under the Biologics Price Competition and Innovation Act of 2009 in the US. Our biosimilar pipeline includes plans for five major US launches by 2020.

According to the Association for Accessible Medicines, generics account for 89% of prescriptions dispensed in the US, but for only 26% of spending on prescription medicine. In 2016, savings to the US healthcare system from generic drugs totaled \$253 billion, while generic drugs saved Medicare and Medicaid \$77 billion and \$37.9 billion, respectively.

In 2017, Sandoz medicines reached an estimated 525 million patients globally, and 264 million prescriptions were dispensed for Sandoz products in the US. We estimate that our generics helped save the US healthcare system around \$13.4 billion in 2016 and \$87.1 billion in the last decade. By 2020, we are projected to contribute \$69.2 billion in savings to the US healthcare system.



Savings from generic drugs to the US healthcare system¹

\$1.67 tn over the past 10 years Estimated savings from biosimilars to the US healthcare system²

\$44 bn over 10 years

¹Generic Drug Access & Savings in the US, 2017, Association for Accessible Medicines

² www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf

Responsible business practices

At Novartis, our vision is to be a trusted leader in changing the practice of medicine, and we must do all we can to build and nurture the trust of our stakeholders. We continually challenge ourselves to meet the highest standards of compliance, integrity and performance in all that we do. Our principles-based professional practices policy helps ensure a sustainable future of innovation for the benefit of patients, as well as society at large and Novartis.

Professional practices

When promoting our products, we have an ethical responsibility to provide accurate, balanced and updated information to healthcare professionals, patients and consumers.

In addition to complying with the PhRMA Code on Interactions with Healthcare Professionals in the US, our marketing practices are guided by our Comprehensive Compliance Program.

The fundamental principles that guide our actions are disclosed on our website at:

→ <u>www.pharma.us.novartis.com/</u> <u>corporate-responsibility/business-conduct</u>

We continually evolve our marketing practices and approach to customer interactions with the aim of maintaining high ethical standards and staying in step with society's increasing expectations. For example:

- We have changed how we incentivize our sales force. We no longer incentivize purely on performance, but also on how the work is done and whether this aligns with our Values and Behaviors.
- We are also changing how we engage with doctors by developing, with their input, a variety of educational options. These include new digital communications tools, as well as impactful changes to traditional in-person events to provide even more doctors with information on the safety and efficacy of our products.

Learn more about our professional practices:

www.novartis.com/our-company/corporateresponsibility/doing-business-responsibly/ ethics-compliance/professional-practices

Payments to healthcare professionals

Novartis collaborates with physicians and healthcare organizations such as teaching hospitals to advance patient care. It is a relationship that has helped deliver numerous innovative medicines and change the way many diseases impact the lives of patients.

Our work together includes a range of activities, from clinical research to sharing best clinical practices. For many products, clinical development activities also continue after the product is made available on the market. As an industry, we make payments and other "transfers of value" to physicians and healthcare organizations to compensate them for their time spent working with us.

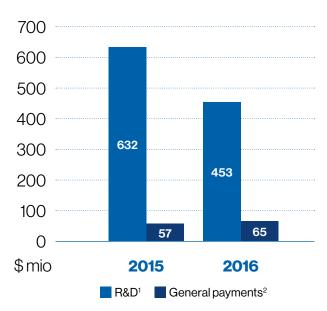
Almost 90% of Novartis payments or "transfers of value" in the US are related to R&D.

Novartis discloses payments and other transfers of value made to healthcare professionals and organizations in the US in line with the Physician Payments Sunshine Act. The vast majority of these transfers of value are related to our research and development efforts, which have yielded one of the most robust pipelines in the industry. Novartis engages physicians in our research efforts as clinical trial investigators and works with hospitals to conduct clinical research studies. As part of this,

we also supply the medicines used in these clinical trials and include the value of these medicines when we report payments and transfers of value under the requirements of the law.

We believe that disclosing payments and transfers of value related to these already well-regulated relationships builds understanding of these collaborations and addresses public concerns about interactions between the medical community and the pharmaceutical industry. Altogether, this reinforces our commitment to high ethical business standards.

Transfers of value by spend category³



- ¹ R&D costs include all the expenditures linked to bringing a new drug to market (or adapting an existing drug), from drug discovery through clinical trials to market approval.
- ² General payments include: compensation, consultancy fees or honoraria; travel; meals; charitable contributions; educational materials and items for physician use; in-kind services such as educational grants or disease management programs, etc.
- 3 2017 data will be published in the Open Payments database in June 2018.

Novartis has a comprehensive program to help collect, track and report payments and transfers of value to physicians, teaching hospitals and research entities across all the Novartis Group companies covered by the act.

We stand by this commitment to transparency and have established rigorous data collection and reporting processes. We also recognize what a complex undertaking it is to track and report this volume of data, and we are committed to ongoing collaboration with the federal government's Centers for Medicare & Medicaid Services (CMS), physicians and teaching hospitals to help ensure we report the information requested.

The relevant reports for healthcare professionals and healthcare organizations prior to 2016 are available on our website.

For more information, please visit:

- www.pharma.us.novartis.com/corporateresponsibility/payments-healthcareprofessionals
- www.pharma.us.novartis.com/corporateresponsibility/payments-healthcareorganizations

All Novartis reports can be found on CMS' website:

→ <u>openpaymentsdata.cms.gov/search/</u> all-entities?name=novartis

Patient group funding

Novartis works with many organizations that advocate for patients around the world, and we disclose the payments we make as part of these relationships. These organizations play a crucial role by informing and supporting patients, as well as working to safeguard the rights of patients and caregivers. Further, patient organizations provide healthcare companies with important advice from their own perspective. Interacting with patient organizations enables Novartis to learn about and understand unmet patient needs as well as barriers to treatment success. This information can guide us in developing therapies and solutions that effectively address these needs.

Novartis discloses the funding provided to patient organizations in the US and other countries by June 30 every year.

Find out more:

www.novartis.com/about-us/corporateresponsibility/doing-business-responsibly/ patient-group-funding

Policy contributions and advocacy

Novartis strives to engage in constructive dialogue with policymakers and other external stakeholders.

Lobbying:

Representing our perspective in the policymaking process and providing policymakers with data and insights enables informed decision-making conducive to improving patient access to innovative medicines. In the U.S., companies are required to report expenditures relating to their federal lobbying activities on a quarterly basis to the clerk of the House of Representatives and to the secretary of the Senate. Federal law dictates what constitutes lobbying in terms of expenditures, reporting and registration. The amount disclosed includes the amount paid to registered contract lobbyists as well as fixed costs such as the value of the labor hours spent on lobbying activities by company officials. It also includes overhead expenses for our Government Affairs team, such as office rent, and an allocation of membership dues paid to third-party trade associations with respect to their lobbying activities. In 2017, Novartis spent a total of \$8 640 000 on federal lobbying-related activities.

Registered state lobbyists comply with all reporting requirements as defined by each state.

For additional information about how we conduct lobbying activities, our Guidelines for Responsible Lobbying can be found **here**.

Financial Political Contributions:

Novartis makes financial contributions to support political dialogue on issues of relevance to our industry. Novartis only makes financial political contributions in countries where such contributions by corporations are legal and considered consistent with our commitment to transparency, honesty and

integrity. In the U.S., direct political contributions are only made at the state level in those states where use of corporate funds is permissible by state law and otherwise considered acceptable.

In 2017, Novartis made political contributions totaling \$1 360 957 in the U.S. This figure includes:

- Contributions to state-oriented political groups, as permitted by state law (\$688 047¹);
- Contributions to federal political groups that focus on specific policies or issue areas at the national level, as permitted by federal law (\$50 000);
- Contributions using corporate funds to candidates and political committees at the state level (approximately \$421350²) in states where this is permitted; and
- Contributions from the Novartis Political Action Committee (PAC) to federal candidates, federal party committees, and some state candidates and caucuses, as permitted by law (\$201 559).

The Novartis PAC only uses funds received from individual participating employees (but not from the company) to make political contributions. These contributions are reported monthly to the Federal Election Commission (FEC) and twice a year to the clerk of the House of Representatives and the secretary of the Senate.

Reports disclosing the sum of federal lobbyingrelated activities and PAC contributions are all available for public access and can be found on the respective websites of the Federal Election Commission (FEC), the U.S. House of Representatives' Office of the Clerk and the U.S. Senate's Office of the Secretary.

Find out more:

- → www.fec.gov/data
- http://disclosures.house.gov/ld/ ldsearch.aspx
- → https://soprweb.senate.gov/index.cfm?
 event=selectfields

¹ Receipt of funds by these groups is in full compliance with applicable laws, regulations, and guidelines.

² This number represents the total amount of pledged political contributions in 2017, though the actual value of contributions given was smaller due to the changing nature of campaigns and other administrative issues.

About Novartis Corporation

At Novartis, we discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Our business model reflects this: We aim to create value for patients, healthcare systems and society based on our innovation capability.

We are a global company with strong roots in the US, where we have more than 23 000 full-time equivalent employees in skilled positions across 24 locations. We have four main campuses: East Hanover, New Jersey; Princeton, New Jersey; Fort Worth, Texas; and Cambridge, Massachusetts.

Corporate responsibility at Novartis

Novartis has a strong history of corporate responsibility (CR) activities, and transparent reporting is a central part of our commitment. We have reported on CR since 2000 through our Annual Report and several online and printed materials.

The CR Report consolidates the company's CR reporting and details our progress against our targets. The 2017 report has been prepared in accordance with the GRI Standards: Core option.

View our 2017 CR Performance Report:

→ <u>www.novartis.com/sites/www.novartis.com/files/novartis-cr-performance-report-2017.pdf</u>



