Novartis in Society 2018 US Report

NOVARTIS

Contents

2018 Highlights

23 000

Full-time equivalent employees in the US, of which 6 700 are employed at our US-based R&D sites

$3.3 BN

Invested in R&D in the US, representing 37% of our global R&D spend that totals $9 billion

4

FDA breakthrough therapy designations received by Novartis in 2018

590 000

Patients received support through our copay assistance program in 2018

273 000

Patients received free medication valued at over $5.8 billion through the Novartis Patient Assistance Foundation Inc. over the past five years

Foreword

We live in a dynamic and hopeful time, as the frontiers of medicine are being constantly pushed forward by scientific discoveries and disruptive technologies. It is also a time of uncertainty and concern, as societies grapple with the challenges of access and affordability to ensure that the benefits of healthcare innovation reach as many people as possible.

In this report – our third since 2017 – we seek to illustrate how Novartis is taking a leadership role in driving the transformation of medicine, while also pursuing innovative approaches to making pharmaceuticals more affordable and accessible. We believe these priorities are tightly interlinked and key to our purpose of reimagining medicine to improve and extend people's lives.

Novartis is accelerating the pace of science and innovation on a variety of fronts. For example, we are investing significantly behind exciting new cell and gene therapies, which could represent a major transformational shift away from traditional approaches to managing chronic diseases with ongoing treatment regimens, in favor of one-time potentially curative therapies. These new treatments are showing great promise against several deadly and devastating illnesses and hereditary conditions.

The implications of this shift for our healthcare system are enormous, and it is important to prepare for them now. For example, these new treatments can be very expensive, which is why Novartis is pursuing novel approaches to pricing them responsibly. By pricing medicines according to the value they deliver to patients as well as society, we can help ensure they reach the people who need them while at the same time incentivizing investment in tomorrow's breakthrough therapies.

We also are harnessing the power of advanced therapy platforms and data science to drive the next wave of medical innovation. This report outlines some of our investments in new data platforms and methodologies that are changing the way we discover and develop medicines, interact with medical professionals and patients, and expand access to healthcare.

Patient access remains a top priority at Novartis, starting with our commitment to integrate access strategies into all our new medicines launches. To help us realize this goal, we recently implemented a set of comprehensive Access Principles that govern our R&D strategy, our affordability efforts, and our focus on strengthening the healthcare system more broadly.

I am particularly inspired by some of the creative ways Novartis associates are doing their part to help expand patient access to quality healthcare. For the second year in a row, associates in our Sandoz Division have launched a global competition inviting inspirational ideas that use digital technologies to solve healthcare access challenges.

Finally, when it comes to delivering on our commitments to patients and other stakeholders, we know it is not enough to have good intentions and well-executed strategies; we also must demonstrate responsible business practices rooted in strong ethics and values. To reinforce these practices, we recently implemented a new Professional Practices Policy for all our associates worldwide.

Thank you for your interest in Novartis. We pledge to remain open and transparent as we continue to reimagine medicine to improve and extend people's lives.

Sincerely,
Thomas Kendris
President, Novartis Corporation, and US Country and Legal Head

Thomas Kendris

WE WELCOME YOUR FEEDBACK:

→ uscorporate.communications@novartis.com

Science and innovation

Our researchers combine imagination with the rigor of collaborative science to find better treatments for disease. Benefitting from our continued focus on innovation, Novartis has one of the industry's most respected pipelines with more than 200 projects in clinical development. We aim to lead the digital revolution in healthcare by harnessing the power of data science and digital technology in our R&D organization and across the enterprise.

Novartis employs more than 23 000 scientists, physicians and business professionals focused on finding innovative treatments and bringing them to patients. Our teams harness new inventions and knowledge to discover and develop transformative therapies. We place big bets, prioritize our resources, and find – or build – new tools to make progress where others have failed. And we're changing the definition of a medicine in the process.

Data science and digital technologies

Novartis is going big on data and digital. Our aim is to transform how we operate, and we are building a foundation to enable the large-scale adoption of technologies such as artificial intelligence, remote sensing and digital therapeutics. These and other digital technologies are in turn driving a new wave of scientific and medical innovation. They bring powerful new tools to every aspect of our work, from the lab to our interactions with doctors and patients.

For example, we're leveraging smart phones, electronic health diaries and wearable devices to improve our research as well as the patient experience. In some cases, it's possible to collect comprehensive data from patients without requiring them to visit clinical trial sites at regular intervals. To this end, we are collaborating with startup companies such as Science 37 that design decentralized clinical trials, which are more convenient for patients.

Digital technologies are changing what the word "medicine" means. In March, we announced a collaboration with Pear Therapeutics, a pioneer in prescription software applications to develop mobile apps to treat patients with specific diseases. In November, we launched *reSET®*, the first and only FDA-authorized Prescription Digital Therapeutic (PDT) that uses technology to strengthen Substance Use Disorder (SUD) therapy. *reSET* delivers cognitive behavioral therapy, contingency management and fluency training to support patient recovery. In December, we received FDA clearance of *reSET-O™*, *which* is indicated for patients with Opioid Use Disorder (OUD).

Novartis is committed to playing its part in expanding access to healthcare solutions around the world. Prescription Digital Therapeutics (PDT), by definition, can increase access by providing treatment immediately when and where patients have their mobile device, rather than the temporal aspect of when a patient can physically schedule and see their clinician. It does not replace the role of the clinician, but certainly can help to offer standardized and enhanced care for SUD/OUD patients, and by providing particular benefit in geographies where access to care is currently inconsistent or unavailable.

We are able to take advantage of these new therapeutic agents which can improve patient outcomes and reduce the burden of illness; and at the same time, can create more seamless, customer experiences for patients and providers alike.

New technology platforms

The rise of digital therapeutics is just one illustration of how medicines today are taking different forms from conventional pills and injections. Another example of this is our flagship cell therapy, *Kymriah*, a chimeric antigen receptor T-cell (CAR-T) therapy that's generated by removing a patient's own white blood cells, reprogramming them to recognize cancer, and then reinserting them into the body.

In August 2017, this "living drug" became the first CAR-T therapy approved in the US, providing a much-needed treatment option for pediatric and young adult patients with a particular type of acute lympoblastic leukemia (ALL). In May, we received approval in the US for a second indication: a particular type of relapsed or refractory large B-cell lymphoma in adult patients. *Kymriah* was also approved for these patient populations in the EU and beyond in 2018.

For decades, researchers have pursued various ways to utilize the human immune system to fight cancer. Through the innovation and perseverance of these researchers, autologous CAR-T (chimeric antigen receptor T cell) therapies were discovered. Individualized CAR-T therapy uses a patient's own immune system to fight certain types of cancers. A patient's T cells are extracted and reprogrammed outside of the body to recognize and fight cancer cells and other cells expressing a particular antigen.

Our teams are designing and developing next-generation CAR-T therapies with the potential to target more than one protein on cells. Researchers are also working to apply CAR-T technology to other tumor types, streamline our manufacturing processes, and further increase manufacturing capacity in an effort to help more patients.

In addition to growing our CAR-T pipeline, we're investing in a platform that facilitates the genetic reprogramming of cells inside the body. In 2018, we closed deals with biotech companies that have deep experience with adeno-associated viruses (AAVs), the tool behind a new wave of gene therapies. In May, we acquired AveXis Inc., including its lead product candidate, AVXS-101, an AAV-based gene replacement therapy designed to treat a neurodegenerative disease called spinal muscular atrophy (SMA), the leading genetic cause of death in infants.

Earlier in the year, we entered a licensing agreement with Spark Therapeutics to register and commercialize their product *Luxturna* (voretigene neparvovec) – the first AAV-based therapy approved by the FDA – in markets outside the US. *Luxturna* is designed to restore vision in patients with mutations in both copies of the RPE54 gene, a rare genetic condition that leads to total blindness by the time patients are in their mid-30s.

Radioligand therapies (RLTs) represent another promising new area for Novartis. These are targeted drugs that are designed to deliver radiation to tumors. We recently acquired Advanced Accelerator Applications (AAA) and its portfolio of products. AAA's treatment for gastroenteropancreative neuroendocrine tumors, a peptide receptor radionuclide therapy called *Lutathera*, was the first RLT of its type to receive approval in the US and Europe. Additional RLTs are under development targeting other tumor types. In December 2018 we also acquired Endocyte, a company developing similar technology to treat prostate cancer.

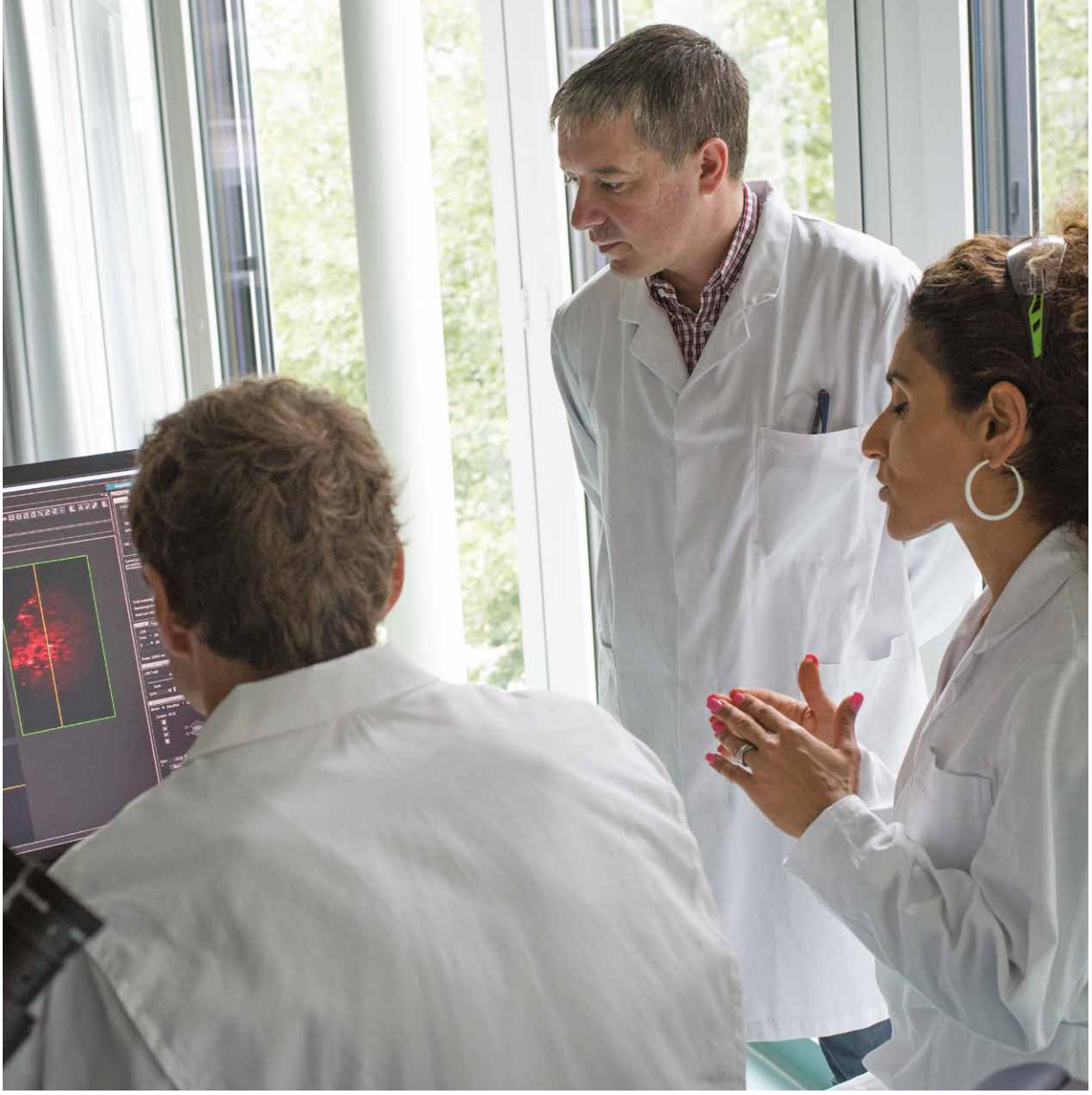
Advancing transformative therapies

Conventional pills and injections continue to bring tremendous benefit to patients and society. Our teams focus on advancing small molecules and biologics with the potential to make a big difference for patients. In 2018, we received key approvals of products for diseases with limited treatment options.

- In partnership with Amgen, we received approval for *Aimovig* (erenumab) in the US, the EU and other markets for migraine prevention. Novartis co-commercializes *Aimovig* with Amgen in the US and Novartis has the exclusive rights to *Aimovig* outside the US, except for in Japan. Migraine affects one in ten people and is the third leading cause of disability in people under 50. *Aimovig* blocks a protein signal that is believed to trigger the excruciating pain and other symptoms of migraine. In clinical trials, many patients on *Aimovig* report more than a 50% decline in their monthly number of migraine days.

- *Gilenya* (fingolimod), our oral treatment for relapsing remitting multiple sclerosis (MS), received additional approval in the US and EU in 2018 as the first therapy for young patients with the disease. Young MS patients frequently suffer double or triple the relapse rates of adults, and clinical studies have shown that *Gilenya* reduces these rates by approximately 82% compared to interferon beta-1a, a standard MS treatment.

- We received a new approval for *Kisqali* in the US for women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer. *Kisqali* is now the only CDK4/6 inhibitor approved for use with an aromatase inhibitor for the treatment of pre-, peri- or postmenopausal women in the US. It's also approved for use in combination with fulvestrant as both first- or second-line therapy in postmenopausal women.



- Our combination treatment, *Tafinar* + *Mekinist*, for melanoma received several approvals – including in the US and EU – for an additional indication as an adjuvant therapy for patients with a BRAF V600 mutation. Of the roughly 200 000 melanoma diagnoses made each year, nearly half of these are driven by a specific genetic mutation called BRAF. *Tafinar* + *Mekinist* is one of the only combination treatments available as an adjuvant for these patients, and clinical trials have shown that this option can be used to reduce the risk of death or cancer reappearance after tumors are removed via surgery.

We took important steps in 2018 to focus our company on innovative medicines. In addition to selling our stake in the consumer healthcare joint venture with GSK, we announced plans to spin off our Alcon eye care division in 2019, pending final approvals, while at the same time maintaining our strong position in ophthalmic pharmaceuticals. Our Sandoz generics division moved to optimize its core generic business, announcing plans to sell a portfolio of about 300 medicines and dermatology products in the US to Aurobindo.

Value and pricing

Across Novartis, our associates are working to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. We share the concerns about the cost of healthcare and the affordability of medicines. Novartis has taken the lead in implementing new pricing and reimbursement models to reflect the value our innovative treatments bring to patients and society. Our goal is to help patients get the medicines they need, when they need them, at prices they can afford.

Accelerating the transition to value-based healthcare

Novartis has long supported the use of value-based pricing principles in the US healthcare system. We believe this approach is one of the solutions to delivering sustainable healthcare. In value-based healthcare, all stakeholders are incentivized to deliver the best possible outcomes for patients, healthcare systems, and society. Resources can be shifted away from wasteful medical interventions to those that add the most value. This can result in a system that better supports patients, protects their access to medicines, and provides overall savings to the healthcare system.

We believe it is important to accelerate society's shift to value-based healthcare. We think medicines should be priced and paid for based on four key outcomes that they can deliver: improvements to patients both clinically and in terms of their quality of life, and the benefits they offer to the healthcare system and society as a whole. This approach could lead to fair reimbursement for medicines and could enable the continued support of ongoing research and development for new innovative, lifesaving treatments.

When pricing new products in a value-based manner, we advocate for a system that affords patients broad access to these products with minimal benefit design barriers, such as minimal use of prior authorizations, step edit methodologies and reasonable patient out-of-pocket costs. In this way, drugs that demonstrate value and are priced accordingly would be unhindered in their ability to deliver that value to patients and to society. Specifically, models like this would encourage the use of drugs that, when partnered with useful programs and interventions like digital technologies, have a discernable and dramatic beneficial effect on the healthcare system. These benefits could include driving improved patient outcomes, lowering drug costs, and increasing the sustainability of the healthcare system as a whole.

We recognize that the US healthcare system will take time to evolve to this new model. However, we plan to continue to demonstrate leadership by continuing to use innovative, value-based pricing and contracting arrangements (e.g., outcomes-based contracts, indication-based pricing and long-term financing models).

Importance of value-based pricing for cell and gene therapies

Today we are entering a new and exciting era in medicine with the emergence of highly effective and potentially curative cell and gene therapies. These therapies present one of the greatest recent advances in modern medicine, putting within our grasp treatments that can reverse some forms of congenital blindness, potentially cure some cancers, and save children from certain death from certain genetic neurological conditions. Yet we face a fundamental challenge: how to pay for these therapies and make them available to patients in need.

Our current healthcare system pays for most medicines over months and years because of the chronic nature of the diseases these medicines treat. Cell and gene therapies, however, are mostly one-time treatments that are potentially curative, potentially extending patients' lives and delivering significant improvement in the quality of their lives. These new treatments are developed, manufactured, distributed and administered in fundamentally different ways from the medicines that preceded them. They require a new pricing and reimbursement model that can support their continued development while also helping ensure access to patients.

We believe a value-based approach to pricing can help achieve this critical balance. We have adopted this model with *Kymriah*, our transformational personalized treatment for children and adults suffering from certain deadly blood cancers. These therapies can also prove to be cost effective for the broader healthcare system, with patients requiring less frequent hospital-

izations. The Institute for Clinical Economic Review (ICER) – an independent expert body that assesses cost effectiveness of medical treatments – has assigned a cost effectiveness value of up to $1 688 000 for *Kymriah* for its use in children. Considering the significance this treatment offers to patients and the healthcare system more broadly, we set the *Kymriah* list price for pediatric use at $475 000 – well below the cost effectiveness value set by ICER – and $373 000 for certain rapidly progressing adult cancers.

In addition to pricing on value, we believe in the use of outcomes-based or pay-for-performance contracts, such as those we have entered into for *Kymriah*, where there is no charge for the therapy unless patients meet certain clinical milestones. We want to continue using outcomes-based frameworks like this one, and hope to pursue other value-based arrangements and models, including indication-based pricing (establishing a baseline benchmark payment for a therapy, providing a higher rate of reimbursement when the therapy performs better for a particular indication), as well as, long-term financing that spreads the cost of a one-time therapy over multiple years. These changes would require healthcare systems to adapt their current approach to payment, and we look forward to working with public and private sector partners to test and evaluate these innovative approaches.

As a pioneer in the shift to value-based pricing for medicines, we want to accelerate and broaden this process, and believe it is key to ensuring better outcomes for patients along with a more affordable and sustainable healthcare system for our society.

Managing price adjustments responsibly

At Novartis we aim to price our medicines responsibly, based on the value they deliver to patients, healthcare systems and society. In the US we recently implemented guidelines for limiting average net price increases across our portfolio to the healthcare inflation rate, and we publish average price increases annually in this report.

-1.1%

decrease in our net prices, on average, across our portfolio

US product portfolio[1] – % change vs. prior year[2]

	2014	2015	2016	2017	2018
Total gross price change[3]	9.9%	9.3%	6.2%	5.4%	5.6%
Total net price change[4]	5.3%	1.3%	-2.0%	-2.1%	-1.1%

1 US product portfolio for 2014 to 2018 includes all medicines sold by the US Innovative Medicines Division, including Alcon Ophthalmics products, and all generic medicines sold by the US Sandoz Division.

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-over- year 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.

In 2018, the average gross price increase across our portfolio was 5.6%. However, our net prices over the same period decreased by 1.1%, on average. 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.

-49.8%

the total annual rebates and discounts on Novartis products

	2014	2015	2016	2017	2018
Total US rebates and discounts[1,2]	-43.3%	-45.8%	-47.7%	-49.5%	-49.8%

In the US, the total annual rebates and discounts on Novartis products (both innovative medicines and Sandoz generics) increased from 43.3% in 2014 to 49.8% in 2018.

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.

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

KEY CORPORATE PUBLICATIONS:

→ www.novartis.com/news/publications

Patient access

Access in action: Integrating patient access strategies into all new medicines launches

Novartis is committed to making our medicines accessible and affordable to as many people as possible. We have embarked on a journey to fundamentally shift the way we do business and reimagine how to expand access to critical healthcare innovations. To achieve this, we recently implemented a set of Access Principles to help ensure that every new innovative medicine we launch has an effective access strategy. This includes adopting innovative pricing and access models, refocusing research and development based on society's healthcare needs, and supporting approaches to strengthen healthcare systems.

Research and development

As we research and develop new drugs, we consider how to get them to more people as quickly as possible, regardless of where they live. We strive to assess our product portfolio against the unmet needs of underserved populations and integrate these needs, as appropriate, into our drug discovery and development strategy.

Affordability

We strive to make our medicines available by considering both effective affordability strategies and innovative solutions to disease management, as well as off-patent solutions to complement our innovative medicines portfolio.

Strengthening healthcare systems

A treatment is only as good as the system that delivers it. We 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.

Starting in 2018, we began measuring progress on expanding access as a key evaluation of success for our leaders and employees, including our CEO. We know that changes like these will take time and not be easy. No single organization alone can solve the access to healthcare challenge, but Novartis is committed to helping accelerate progress.

Helping insured patients afford their medicines

Novartis has a number of programs in place to make our medicines more affordable for 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 ($1 per day) through retail or mail order for the vast majority of our branded and biosimilar products. This includes our cancer portfolio. Our copay assistance programs are subject to any limits imposed by a patient's individual health plan, pharmacy benefits manager or employer, and where allowed by law.

Novartis is currently unable to provide patients covered by government healthcare programs (e.g., Medicare and Medicaid) with copay assistance, due to existing regulations. Medicaid patients already have the benefit of low out-of-pocket expenses for their medicines, but the picture is quite different for many people on Medicare who face high drug costs. 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 with out-of-pocket costs can help reduce the level of unfilled or abandoned prescriptions and support patients' ability to adhere to their medicines as prescribed. This could

In 2018, Novartis copay assistance programs assisted nearly 590 000 patients.

FIND OUT MORE ABOUT OUR ACCESS PRINCIPLES AT

→ www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/access-principles

"Thank you for getting my life back"

Ursula and Robert are two patients who share a common challenge: they can't afford their medicines. In Ursula's case, she came down with a serious neurological disorder that forced her to quit working and lose her health insurance. Robert was a retired educator who found he could not pay for his treatment for a grave heart condition. In both cases, they contacted Patient Assistance NOW, a service provided by Novartis to help patients find access programs that will get them the medicines they need free-of-charge. Now, thanks to treatment for her neurological condition, Ursula is gardening, taking walks and making plans for the future. Robert is living his life fully as well, secure in the knowledge that "people out there care for me", by making sure he has access to his cardiovascular therapy. In these and thousands of other cases, Novartis and other pharmaceutical companies are making free medicines available to people in need, regardless of their ability to pay for them.
Says Ursula about the program: "thank you for getting my life back."

ultimately impact longer-term health outcomes and reduce overall costs for the US healthcare system.

Uninsured and underinsured patients

In the US, the Novartis Patient Assistance Foundation Inc. (NPAF) provides medicines at no cost to eligible US patients who are experiencing financial hardship and have limited or no prescription drug coverage. The number of patients needing help has continued to increase; in 2018, the foundation provided more than USD 1.9 billion in free medicines to more than 68 000 patients in the US, covering more than 65 medicines from our portfolio. Over the past five years, free medication valued at roughly over USD 5.8 billion has been provided to around 273 000 patients.

We continue to look for opportunities to improve the efficiency of NPAF programs, using innovative technology solutions to enhance the patient's journey. Improvements such as automation in the income check process and use of e-signatures, enable patients to move through the required application process more quickly and easily, speeding up their onboarding into the program and helping them get the medicines they urgently need.

We also realized that in certain indigent areas of the US, there are opportunities for NPAF to partner with others – for instance, with the nongovernmental organization, Direct Relief, to provide bulk retail pharmaceutical medications to a network of qualified institutions that handle the enrollment and processing of individual medication orders. As Direct Relief supports various safety net clinics, this more efficient system allows patients to walk in and receive the medicines they need almost immediately, filling a critical gap in the system.

Patient support services

Many patients find it difficult, confusing and at times stressful to get access to their medications. Novartis offers tools and support designed to 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
→ www.patientassistancenow.com
→ www.pap.novartis.com

Novartis Pharma Universal Co-Pay Program
→ www.copay.novartispharma.com

Novartis Oncology Universal Co-Pay Program
→ www.copay.novartisoncology.com

Novartis Oncology Patient Support
→ www.patient.novartisoncology.com

Furthering affordability with off-patent medicines

At Sandoz, the Novartis generics division, we are transforming our portfolio with biosimilars, value-added medicines (VAMs) and digital therapeutics, while driving sustainable growth in those segments of the global core generics market where we can demonstrate superior development, manufacturing and go-to-market models. We are driven by our strong ambition to pioneer novel ways to improve access to medicines.

According to the Association for Accessible Medicines (AAM), biosimilars have the potential to improve the quality of life for American patients, while at the same time saving the health system billions of dollars each year. Biosimilars are estimated to save the US healthcare system $54 billion over ten years[1]. Sandoz is leading this effort, with eight biosimilar medicines approved worldwide including three in the US. In 2018, one of our biosimilar medicines became the first biosimilar in the US to overtake market share of the originator reference product, and remains number one in volume share.

The Sandoz value-added medicine portfolio includes drug device combos, that address critical unmet needs in the market. For example, in early 2019, we introduced Symjepi™, to meet a critical need in a market that has been dealing with epinephrine shortages and high-priced products for emergency treatment of anaphylaxis for quite some time. We also develop and produce complex generics as viable alternatives for patients, providers and payers, including ready-to-use, IV formulation and long-acting injectables.

We estimate that our medicines helped save the US healthcare system around $13 billion in 2017 and $93 billion in the last decade[2].

$13 BN

estimated savings from our off-patent medicines to the US healthcare system in 2017

$93 BN

estimated savings from our off-patent medicines to the US healthcare system over the past 10 years

[1] Mulcahy AW, Hlávka JP, Case SR. Biosimilar cost savings in the United States: initial experience and future potential. Santa Monica, CA: Rand Corporation, 2017. www.rand.org/pubs/perspectives/PE264.html

[2] Sandoz savings estimated based on Sandoz value share in the generic market as per IQVIA National Sales Perspectives data applied to the total savings generated to the US healthcare system, as published in the AAM "2018 Generic Drug Access and Savings in the US" report.

Responsible business practices

Novartis believes that responsible business practices are a critical part of our broad commitment to ethical conduct and strong values. To reinforce these practices, we have implemented a new Professional Practices Policy for all our associates worldwide.

And we have taken other steps to help ensure that our engagement with patients, policymakers and other stakeholders is ethical and transparent. We aim to be a trusted leader in changing the practice of medicine by challenging ourselves to meet the highest standards of compliance, integrity and performance in everything we do.

Professional practices

In March 2018, Novartis implemented a new worldwide Professional Practices Policy built on five ethical principles that are intended to guide our associates in their decision-making both externally and internally. These principles are:

- **Put patients first.** All interactions with our customers must ultimately benefit patients by enhancing the standard of care, raising awareness about diseases and their treatment options, and contributing to the ethical delivery of care. We are committed to always treating patient information with respect, protecting confidentiality, obtaining informed consent where required, being transparent with patients and protecting their safety, including by promptly reporting product-related risks or complaints.

- **Fund responsibly.** External funding – including grants, donations and sponsorships – must only be given to legitimate organizations. This support must be provided in a way that protects our reputation, aligns with society's expectations, and is consistent with our purpose to discover new ways to improve and extend people's lives.

- **Act with clear intent.** All our activities must have clear and transparent objectives that are accurate, truthful, not misleading, and appropriate for their intended context. This is important for our promotional and nonpromotional efforts, which help ensure our products are developed to meet the needs of patients, and also advance scientific understanding of disease and facilitate discussion around appropriate use of products. Non-promotional activities should never be conducted in a way that are intended or perceived to be promotional.

- **Engage appropriately.** We cannot offer, approve or provide anything of value with the intent or consequence of inappropriately influencing or rewarding our customers for using Novartis products. Any compensation for healthcare providers or other customers who are helping us research, develop and/or promote our products must be for a bona fide service, consistent with

MORE INFORMATION ON THE PROFESSIONAL PRACTICES POLICY IS AVAILABLE AT

→ www.novartis.com/our-company/corporate-responsibility/ethics-risk-compliance/professional-practices

fair market value, properly documented and accounted for, and disclosed where required. Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

- **Research for the right reason.** Research and development (R&D) must only be conducted to address valid medical or scientific questions aimed at enhancing patient care. We must always respect and protect the rights, safety and well-being of patients and animals and safeguard the integrity and validity of the data obtained. R&D activities must follow established ethical and scientific standards and be conducted by qualified investigators. They must never be promotional in nature.

These principles translate into specific policies in the areas of clinical research, pricing and market access, pre-approval communication and scientific exchange, promotional interactions and content, events, fees for services, interactions with patients and patient organizations, extending funding and other areas.

When promoting our products, we have an ethical responsibility to provide accurate, balanced and up-to-date information to healthcare professionals, patients and consumers. One of the ways we are doing this is by supporting the guiding principles on Direct-to-Consumer (DTC) advertising that were recently issued by the Pharmaceutical Research and Manufacturing Association (PhRMA), the industry's trade group.

These principles represent another step forward towards helping ensure that patients have all the information they need to understand their out-of-pocket costs to make the most appropriate and informed decisions about their prescription medicines.

Policy contributions and advocacy

With healthcare at the forefront of conversations and debates across the country, Novartis believes it is important to actively engage with policy leaders and other external stakeholders.

MORE INFORMATION ON THE DTC ADVERTISING PRINCIPLES CAN BE FOUND AT

→ www.phrma.org/codes-and-guidelines/direct-to-consumer-advertising-principles

Lobbying

Through lobbying, Novartis is able to pursue constructive dialogue with officials to assist them in making informed decisions on healthcare policy, such as ensuring patient access to innovative therapies. Armed with data, insights, best practices, and ways to improve patient outcomes, the company's government affairs team aligns our strategic work with sound policy initiatives to help achieve the most productive regulatory and legislative environment for our business and the patients we serve.

Regarding the use of external lobbying-related resources, we understand more than ever the importance of strengthening the relevant contracting and due diligence processes. For example, before Novartis engages political consultants, we now secure an independent third-party due diligence report.

Federal and state law dictates what falls under lobbying in terms of expenditures, reporting, and registration, which is further clarified through guidance from the Senate and House of Representatives. The intent of the federal law is to provide transparency and accountability regarding persons who appear before the federal government advocating for policies

that would protect or benefit their constituencies. Not all government affairs related activities are considered lobbying, but many of them are. Included in the amount disclosed are labor hours of all Novartis officials who engage in lobbying, consultants and third party expenses and the portion of trade association dues related to lobbying. Registered state lobbyists comply with all reporting requirements as defined by each state.

Financial Political Contributions

Novartis engages with political leaders on issues of importance to our industry, such as patient access, intellectual property and digital health. 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 US, 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 2018, Novartis made political contributions totaling $1 145 100 in the US. This figure includes:

- Contributions to state-oriented political groups, as permitted by state law ($321 000[1]);
- Contributions to federal political groups that focus on specific policies or issue areas at the national level, as permitted by federal law ($25 000);
- Contributions using corporate funds to candidates and political committees at the state level (approximately $530 100[2]) 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 ($269 000).

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 lobbying-related 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 US House of Representatives' Office of the Clerk and the US Senate's Office of the Secretary.

FIND OUT MORE

→ www.fec.gov/data/

→ disclosures.house.gov/ld/ldsearch.aspx

→ 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 2018, though the actual value of contributions given could be 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.

Global health and corporate responsibility at Novartis

Novartis has a strong history of global health and corporate responsibility (GH&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 Novartis in Society report (formerly the CR report) consolidates the company's GH&CR reporting and details our progress against our targets. The 2018 report has been prepared in accordance with the GRI Standards: Core option.

VIEW OUR NOVARTIS IN SOCIETY 2018 REPORT:

→ www.novartis.com/sites/www.novartis.com/files/novartis-in-society-report-2018.pdf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