Improving lives with medical cannabis
How access to new treatment options can help patients in Canada
Access to healthcare is arguably the single largest unmet medical need. This is still true, despite all the advances made by modern medicine. However, the nature of the access challenge continues to evolve. And players across the healthcare sector need to evolve with it to meet the new challenges.

Let’s start with what hasn’t changed. Two billion people worldwide still lack the medicines they need. 400 million still lack access to essential health-related services. And national healthcare budgets continue to increase at unsustainable rates.

But two major new trends now complicate this picture.

First, we are witnessing a radical change in the global disease burden. Not so long ago, infectious diseases were the leading cause of mortality. Today, even in poorer countries, more deaths are caused by noncommunicable diseases (NCDs).

The growing prevalence of these complex, chronic conditions leads to steadily increasing demand for “high-end” therapies, ranging from complex generics and value added medicines to biosimilars. (Let’s not forget, most medicines today are off-patent, which is the main reason that national healthcare budgets did not implode a long time ago).

Second, and in parallel, there is a growing need to balance the traditional concept of increasing access with that of ensuring responsible use of medicines by avoiding overuse, underuse and abuse (not least by ensuring stable and reliable supply chains). Most pressingly, the looming threat of antimicrobial resistance (AMR) is focusing attention on the possibility of a world “beyond antibiotics.” That’s why Sandoz, as the leading provider of generic antibiotics, is working across stakeholder groups to find pragmatic, scalable solutions to this global threat.

The US opioid crisis – the growing number of hospitalizations and deaths from opioid abuse – is another example of how solutions that worked in the past may no longer be good enough in the future. Today there is an opportunity to move millions of sufferers away from traditional “medicine-only” pain management solutions to, for example, potentially game-changing new digital therapeutic options. That’s why I’m so excited about our pioneering partnership with Pear Therapeutics, to offer fresh hope for sufferers of substance use disorder.

Ensuring universal access to healthcare remains one of the leading challenges of our times. But the nature of access is evolving – and players across healthcare must adapt rapidly to meet the unmet needs of tomorrow. To coin a phrase: If we want things to stay the way they are, something has to change.
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Leprosy is a chronic, neglected tropical disease caused by a mycobacterium. Untreated, leprosy can cause permanent damage to the limbs.
Leprosy, LEARNS and laughter

“I met this woman in a remote community in the Philippines. Her leprosy diagnosis was delayed, leading to physical disability and deformity. Despite her tremendous suffering, she was successfully treated – still smiling and laughing, she survived and so, too, did her hope and positive outlook on life. Although free multidrug therapy has reduced the number of leprosy patients globally, the number of new patients has plateaued in the past decade at about 200,000–250,000 annually. In the Philippines, about 2,000 new leprosy patients are still detected each year. Today, the ‘last mile task’ is helping to reduce delays in diagnosis, so others can receive treatment sooner and avoid disability.

Launched as part of a Task Force for Leprosy by the Philippine Department of Health and the Novartis Foundation, the Leprosy Alert and Response Network System (LEARNS) was first implemented in the Iloilo province and now covers 27 provinces in nine regions. It is a mobile phone-based system that allows frontline providers to send images of suspected leprosy lesions and symptoms via SMS to a specialist, helping to reduce delays in diagnosis and treatment.”

Dr. Alexander Kumar, global health medical doctor and professional photographer from London, UK
On the many rural roads outside of Rwanda's capital, Kigali, delivering supplies – including medicines – has been extremely challenging.
“There’s a linear relationship between how far away you live from a city and your expected lifespan. Our hope is that technology can solve those kinds of inequalities.”

Keller Rinaudo, CEO Zipline
A drone drops a parcel containing blood packages to the Kabgayi Hospital in Rwanda.
Drones for health – How ‘sky ambulances’ save lives

To ensure access to blood units for citizens in need, the government of Rwanda has implemented an innovative solution. In a partnership with a California start-up, drones deliver medical products in this East African country – and similar projects are improving outcomes for patients all over the world.

Hundreds of people lined a fence in the Muhanga district, Rwanda, and were staring curiously at a lawn where a small plane, not bigger than an adult’s arm span, was placed on a metal ramp. Their eyes tried to follow as, within seconds, the tiny plane soared into the air and disappeared into the horizon.
At the same time, dozens of kilometers away, beyond impassable mountains and washed-out roads, 24-year-old Françoise lay in a bed at Kabgayi Hospital, fighting for her life after giving birth. It was in late 2016 when Françoise was hemorrhaging, which is the leading cause of maternal death in low-income countries. “Something had gone wrong during the birth, so afterwards they kept stitching me again and again. It wasn’t until the fourth try that they were successful,” she remembers. In the meanwhile, Françoise had lost a lot of blood. But the hospital didn’t have her blood type in stock – and she needed blood fast to survive. What she didn’t know at that time was that a life-saving treatment was already on its way, carried by the drone that had launched in Muhanga just a few minutes before.

What might sound like an extraordinary event has saved hundreds of lives across Western Rwanda. There, a fleet of medical drones serves 21 hospitals, providing instant access to blood products for eight million people. Air transportation like this clearly has its advantages in this East African republic, which is also known as the “country of a thousand hills.” While the 1,000-kilometer long main road network is paved and well-developed, many side roads are in very poor condition. This variability makes some regions difficult to integrate into a logistics plan. The result had been area hospitals needing multiple hours to pick up blood at a regional center.

Rwanda is far from alone in this problem: Throughout the developed and developing world, access to life-saving and critical health products is hampered by what is known as the last-mile problem – the inability to deliver needed medicine from a city to rural or remote locations because of inadequate transportation, communication or supply chain infrastructure. The result is that all too often someone in need of lifesaving care does not receive required medicine. Worldwide, more than two billion people lack adequate access to essential medical products, including blood and vaccines, because extreme terrains and gaps in infrastructure hinder all but the most heroic efforts.

A big bet on smart technology
In saving lives, every second that can be gained is critical. For this reason, the government and the Ministry of Health teamed up with the Silicon Valley start-up Zipline in 2016. Because Zipline offered a solution to blood shortages in rural areas, the government of Rwanda didn’t hesitate. Together, they now operate the world’s first national drone delivery system to carry urgent medicines to patients in need.

“When we ask the children at our operating site what they think about the drones, they say they are the ‘sky ambulances’.”

Keller Rinaudo, CEO Zipline

“Most people think that advanced technology cannot start in Africa,” says Keller Rinaudo, CEO of Zipline. “But it was the Rwandan Ministry of Health that made a big bet on the potential of this technology and signed a contract with us to deliver a majority of the country’s blood on demand.” The idea behind the venture is both smart and effective.

Eliminating waste, gaining access
Zipline drones – also called Zips – are specifically designed for their task. Compared to quadcopters, for example (another type of drone, with four rotors and four arms ending in propellers), battery-powered Zips are more efficient for long distances: They can deliver reliably to any site within an 80-kilometer radius on a preprogrammed route and with real-time monitoring. In contrast, a quadcopter can reach only a radius of approximately five to ten kilometers. This makes a huge difference when trying to serve an entire nation like Rwanda. With a quadcopter, it would be possible to reach an area covering around 10,000 people – but Zipline drones can cover areas of seven million people.
Airplane-shaped drones, known as Zips, deliver medical products within an average time of 30 minutes.
Accelerating from zero to over 100 kilometers per hour in half a second, Zipline drones deliver essential medical products of up to 1.8 kilograms per flight while maintaining the cold chain if needed – in an average fulfillment time of 30 minutes.

These drones also tackle a general problem in health logistics, which is balancing waste and access. “To ensure access, hospitals and health centers stock a lot of medicine so that patients have the medicine they need. But that leads to a lot of waste when the supplies expire,” says Rinaudo. In cooperation with Zipline, Rwanda has escaped this vicious cycle. As in Françoise’s case, it is rarely possible to predict the demand for blood, and it is even more unlikely to know which blood type is needed. “By using our technology, Rwanda has been able to keep more blood in a central location and then provide it immediately to a patient in a remote hospital or health center,” says Rinaudo. “In the last nine months, zero units of blood have expired, and thus been wasted, at any of these hospitals,” he adds. “That’s an amazing result that has not been achieved by any other healthcare system.”

**Access in emergencies and disasters**

The collaboration in Rwanda is an example of the potential that drone technology has in healthcare. These small airborne vehicles can assist wherever infrastructure is poor or when natural disasters block mainland-based transport routes. In fact, this was one of the earliest medical utilizations of drones: Unmanned vehicles successfully delivered small aid packages after the Haitian earthquake in 2012. They were also able to help in humanitarian operations for collecting data and imagery where infrastructure was destroyed or already lacking, such as in the Philippines after a typhoon in 2013. While drones were used sparsely in both situations, they nevertheless demonstrated their usefulness.

To further explore their potential, a partnership between UNICEF and the government of Malawi launched in 2017, creating an air corridor to test the humanitarian and developmental use of drones. This air space in central Malawi will be used as a test site for aerial scouting in crisis situations and for the delivery of medical supplies. It will also use agile quadcopter drones to boost Wi-Fi and cellphone signals.

Drones can also be used in the immediate aftermath of emergencies, including man-made ones, where too many people are injured for rescue services to attend to everyone. In other cases, entering an accident site would be too dangerous, such as in shootings or hazardous outbreaks. For these reasons, scientists at William Carey University in Hattiesburg, Mississippi, US, have developed a Healthcare integrated Rescue Operations (HiRO) drone that can quickly deliver a 20-pound medical kit to emergency scenes. Each supply set includes a smartphone, and the kits
can be adapted for different situations. For example, there is a set for accidents on farms, in the wilderness or anywhere there is a traumatic event.

The rise of airborne medical couriers
As countries around the world face the challenge of delivering medical supplies quickly and efficiently, drones are being launched for a growing range of missions. For example, the Rwandan government’s trust in drone technology has inspired a neighbor to follow its lead. In 2017, Tanzania announced its plans to adapt the Zipline drone delivery system to improve access to essential medicines as well as basic surgical supplies. Up to 2,000 deliveries per day are planned to fly to more than 1,000 health facilities and ten million people across the country.

Of course, lack of access to medical products is not tied to a geography or region. “Millions of people across the world die each year because they can’t get the medicine they need when they need it,” says Zipline CEO Keller Rinaudo. “It’s a problem in developing countries, but also in developed countries.” This is why Zipline has expanded its services to the US. “There’s a linear relationship between how far away you live from a city and your expected lifespan. Our hope is that this type of technology can solve those kinds of inequalities,” Rinaudo adds. The company is already working with the state governments of Maryland, Nevada and Washington, and with leaders on Native American reservations, particularly to reach patients in remote or isolated areas.

But barriers to medical access can also appear in places least expected. Even in high-income countries with a well-developed infrastructure, problems are more likely to be caused by too much traffic. Especially at peak times, medicine deliveries often have no chance of reaching their destination quickly. In urgent medical cases in Switzerland, for example, drones fly above the traffic congestion to transport medical samples from hospitals to laboratories. The initiative, developed in partnership with Swiss Post, the national postal service, is set to launch in 2018 with plans to deliver other medical products as well.

Cheering for the ‘sky ambulances’
Whether flying over jammed roads or impassable mountains, drone technology is improving access to medicine. “From the time the hospital requested the blood to receiving it, less than five minutes passed,” Françoise says. “It was very fast.” While in the hospital, she didn’t know that a drone delivered the blood she received. Today she knows, and she’s a firm supporter. “I feel that everyone should have access to this service. Without it, I would not be here today, and there are many others like me who have benefitted.”

Zipline CEO Rinaudo regularly visits the drone site in Muhanga. Every day, hundreds of Rwandans line the fence of the distribution center to watch operations. The whole crowd cheers for every take-off and landing. “Some kids show up at 6 a.m. to get good seats. When we ask them what they think about the drones, they say they are the ‘sky ambulances’,” Rinaudo notes. “It’s not only the novelty of the drones that makes them cheer. Today they understand what this technology means for them and their families.”

After the blood package has been dropped by paper parachute outside the hospital, it is immediately ready to be used with patients.
Believing in the potential of medical cannabis as a treatment option for various conditions, Sandoz Canada has teamed up with a licensed producer.
“We are investigating the benefits of medical cannabis for improving the quality of life for patients. We have to continue refining and building the existing evidence.”

Philippe Lucas, Vice President of Global Patient Research and Access, Tilray
Pioneering treatment options: How medical cannabis improves patients’ lives

Though not without its critics, medical cannabis has been used as a therapy of last resort. Despite growing evidence that medical cannabis can offer further medical benefits, accessing this treatment can be a challenging process for patients – and can raise questions regarding dosing and treatment planning for medical professionals. Researchers and companies, including Sandoz Canada, are working to improve access to this medicine and related information.
In order to ensure the safety of patients, medical cannabis is produced with meticulous care.
James O’Hara’s illness had taken over his life. A life-long migraine sufferer, in his 50s he began experiencing sudden seizures. For about two weeks after each seizure, O’Hara was left in a state of confusion and with poor memory. “I couldn’t function properly,” he explains from his hometown of Toronto, Canada. His neurologists ran a battery of tests including MRIs and CAT scans. After they diagnosed focal awareness seizures, O’Hara received standard anti-seizure medication. But his seizures continued, no matter which treatment he was given. And the medications brought their own side effects, including exhaustion. “I was completely disconnected from work and my family – and I knew it.”

Purely by chance, an acquaintance suggested that medical cannabis might help. O’Hara knew little about it. However, the more he began to research it himself, the more he became convinced it was worth a try. Out of desperation, O’Hara searched for a physician who was willing to support him in attempting this treatment. “It was a challenge, but I was lucky to find the right doctor.” The results, says O’Hara, were like night and day. “All of a sudden, I was able to control the seizures while functioning better in daily life. To put it simply, I could work more and contribute to my family more.” But, as O’Hara’s overall health stabilized, he says he also began wondering: Why were people not more aware of medical cannabis? Why didn’t more people have access to it?

A complex situation

Now a medical cannabis patient for almost a decade, O’Hara admits that the idea of using cannabis for medical reasons can raise eyebrows. “One issue may be the distinction, legally as well as culturally, between cannabis and medical cannabis,” he points out. A central problem is that some believe that medical cannabis produces a ‘high’ like recreational cannabis. But, in fact, as a patient “you are using medical cannabis as an alternative to traditional medicine.”

It’s not just the public that has questions or lacks information, resulting in uncertainty towards medical cannabis. In Canada, the national health service (Health Canada) has approved the use of medical cannabis, but the Canadian Medical Association (CMA)
Medical cannabis – Its effects on the human body

The endocannabinoid system (ECS)

is a network of receptors spread throughout the human body that are involved in controlling the immune system, memory, appetite, sleep pattern, mood and pain sensations. THC can bind directly to the receptors CB1 and CB2, while CBD exerts its effects more indirectly.

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Sources: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741114/; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2241751/; Tilray

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has not. With this lack of official CMA endorsement, not all Canadian doctors may be comfortable or willing to authorize medical cannabis (see our interview below). Although Canada has legalized recreational cannabis as of October 2018, this does not affect the current regime for medical cannabis.

Once patients find a doctor who will authorize this treatment, they face another obstacle. Canadian patients must order their prescription online from approved producers. Bricks-and-mortar Canadian pharmacies, with live pharmacy professionals, cannot at this time provide medical cannabis. This also means that Canadian patients cannot currently (as of October 2018) get any advice about dosing or contraindications from their local pharmacists.

Looking for answers – filling the gap

This shortage of information about medical cannabis has been a reality around the world for some time. While cannabis has been used as medicine in various cultures for at least 4,000 years, Western civilizations turned their back on this treatment in the 20th century. The precedent was likely set by the US, where cannabis became illegal for any purpose in 1937. Other countries followed the US lead, and cannabis largely disappeared as a recognized means of medical treatment. As
Researchers continue to study the physiological and pharmaceutical effects of medical cannabis to be able to offer patients a safe treatment option.
a consequence, an information gap emerged and developed over the past 80 years.

In order to begin filling this gap, some licensed producers like Tilray are currently conducting clinical and observational studies examining a number of indications, including the use of cannabis extracts in the treatment of pediatric epilepsy, chemotherapy-induced nausea and vomiting, and essential tremors. “The focus of these studies is examining how different doses and ratios of THC (Tetrahydrocannabinol) and CBD (Cannabidiol), both active compounds of cannabis, affect different symptoms and conditions,” explains Philippe Lucas, Vice President of Global Patient Research & Access at Tilray. The cannabinoid THC is psychoactive and may provide analgesia and reduce inflammation in chronic pain, and may combat symptoms such as nausea and vomiting (often a side effect of chemotherapy). However, CBD, a non-psychoactive compound, may be able to lower anxiety, depression and pain.

Strict dosage of medical cannabis may be required to influence various physiological processes of the human body. The central nervous system has a specific ‘network’ of cannabinoid receptors and receptor antagonists, the ‘endocannabinoid system.’ Here, within this system, THC and CBD trigger signals that are involved in immune responses as well as mental and motor actions including appetite, pain-sensation, mood and memory. “Effectively, the human body’s endocannabinoid system has receptors that interact with cannabinoids from the cannabis plant,” explains Lucas. It is this system that mediates the effects on the human body and is, thus, central to the medical use of cannabis. Adds Lucas, “The human body’s endocannabinoid system engages with plant-derived cannabinoids like a lock-and-key.” (See infographic, page 19.)

Alternatives for managing pain
From his office in Nanaimo, British Columbia, Lucas personally investigates a range of applications. As a researcher for the last 15 years, he is interested in “medical cannabis as an alternative to other prescription medications.” He estimates that 80% of the approximately 270,000 Canadian cannabis patients use it for chronic pain and mental health conditions.

Tilray’s research department has multiple studies underway on the broader effects of medical cannabis use, including one called TOPS (the Tilray Observational Patients Study), says Lucas. The data for the study’s first six months has been extremely insightful. “There was a significant rate of substitution for all classes of prescription drugs that we’re tracking – including muscle relaxants, antidepressants, anti-seizure and pain medications,” Lucas explains. Medical cannabis is also being investigated for its potential role in fighting the ongoing opioid crisis in Canada and the US.

Creating access solutions: Informing and supporting
While all of this might be good news for patients suffering from a range of chronic conditions, access to this medicine – and access to information about it – is still required to maximize its potential benefits among doctors and patients. Patient advocates like O’Hara and researchers like Lucas agree. “I think there still is a huge need to educate the general public, policy makers and
Do you prescribe medical cannabis to your patients, and why?

For some of my patients, traditional pharmaceutical treatments weren’t effective, or patients couldn’t tolerate the side effects. So that’s when I first started to prescribe medical cannabis. I continued to prescribe it because of the positive results, with less risk of serious side effects. I educated myself on the endocannabinoid system. And once I understood the underlying physiology, I had to acknowledge that medical cannabis is a scientifically reasonable option for the treatment of certain conditions.

I also support medical cannabis because it’s a multimodal treatment. This means that it can treat more than one symptom with just one medication. For example, in pain management, I am often able to manage someone’s pain and at the same time treat related issues like insomnia and anxiety with one cannabis formulation. So it’s a medication that can also lead to a reduction in polypharmacy, which is the simultaneous use of multiple medications by a patient.

What problems do you see with medical cannabis?

Unfortunately, there is a lot of misinformation about cannabis, even in the medical community, and there continues to be an inherent bias against it due to a variety of political and personal ideologies. There is already a significant body of high-quality evidence to indicate that cannabis is effective in treating conditions including chronic pain, chemotherapy-induced nausea and vomiting, MS spasticity and short-term sleep disorders – and the body of evidence is growing around a host of other conditions.

Undoubtedly, we need more controlled trials to investigate the effectiveness of cannabinoids for the multitude of other conditions that it has the potential to benefit. But, apart from that, we need to consider the double standard – and stigma – regarding medical cannabis amongst some in the medical community: We demand much more rigorous evidence for cannabinoid therapy than we do for other treatments. For example, in Canada, one in nine drugs is being used off-label, meaning that it is prescribed for different indications or types of application than originally approved by the authorities. Within pediatrics, this number rises to 75% of medicines being prescribed off-label.

As physicians, we seem to be okay with this. Although, according to the Canadian health department, Health Canada, 79% of off-label prescriptions were not supported by strong scientific evidence – with “strong evidence” being described as having at least one randomized controlled clinical trial. Off-label prescribing is not prohibited in Canada, and most physicians agree it is essential in ensuring health professionals can pursue treatments that are in the best interest of their patients. There are many examples of innovative uses for existing drugs, and I see a parallel here. I see the positive impact of cannabis therapy on my patients every day, and I question this double standard.
Based on your experience with your patients, does access to medical cannabis improve lives?
To put it simply, medical cannabis works for certain conditions – and for some patients, it is the only medication that is effective. A number of my elderly patients rated their pain as severe enough to limit themselves from gardening, going for walks and spending time with their grandkids. For many, it was also preventing them from getting a good night’s sleep. With medical cannabis treatment, they experience less pain, and they enjoy their lives again. Specifically, I’m thinking of a female patient with chronic pain, who had multiple operations on a tumor on her jaw. For her, this was an access matter: A pain specialist refused to give her medical cannabis, so she was given an opioid that’s a hundred times stronger than morphine - but it wasn’t providing relief. So, she was referred to me. Within a couple of months, we had her pain better controlled, and she was able to completely come off the opioid, by using a cannabis oil.

“I prescribe medical cannabis because it is a scientifically reasonable option for the treatment of certain conditions.”

From my perspective, medical cannabis is a medication that can be effective for treating certain conditions. And when you consider its low risk for serious side effects and its ability to potentially reduce other medications, medical cannabis needs to be considered as a reasonable option. It’s not the only option, but it should be an option.

health care providers in order to help people have better access to this treatment,” says O’Hara.

Fortunately, the situation is changing. The body of anecdotal evidence has increasingly encouraged doctors to consider medical cannabis as a treatment option, and scientists worldwide have been giving it a second look – which has led in turn to a stunning amount of new research work. As an example, according to a summer 2018 article published in the “Deutsche Ärzteblatt” (German Physicians’ Journal, a publication co-owned by the German Medical Association), there are 750 scientific publications on the medical effects of cannabis, and more than 600 cases, open and controlled studies, have been reported since 1970. Just as importantly, 80% of these studies have been carried out in the past 20 years.

Motivated by patient experiences such as O’Hara’s, and by the growing amount of scientific evidence and medical efficacy, several pharmaceutical companies are investigating the medical cannabis stream. At the forefront is Sandoz Canada and its partner Tilray, a licensed producer of medical cannabis. Together, they have partnered to provide greater access to medical cannabis products for Canadian patients. With their experience in manufacturing medicines, Sandoz Canada will help to develop new and innovative medical cannabis products, including new product dosage forms and delivery systems suited to specific medical uses. In addition, Sandoz and its partner will invest in research studies to advance the science in a variety of medical conditions.

Vincenzo Ciampi, Executive Director of Innovation and Strategic Projects at Sandoz Canada, and his team believe that making these products more widely available may improve patients’ health outcomes. In 2016, the team embarked on a journey to further legitimize medical cannabis as a mainstream medicine and trusted treatment option, and to support patients to confidently access quality treatments. Sandoz Canada has a strong vision to distribute these treatment options via pharmacies to further ensure accurate usage and invite consultation throughout treatment. “What we have begun doing is educating the pharmacists about medical cannabis,” continues Ciampi.
Do you prescribe medical cannabis to your patients, and why?
I prescribe medical cannabis for a limited number of conditions and mostly for pain relief. But, for me, it still is a last resort medication, for example in cancer and palliative care. Patients sometimes come to my office asking for medical cannabis as a first line treatment for chronic non-cancer pain after having tried one or two other medications. They often haven’t had physiotherapy or steroid injections or any other type of medication. So I send them back to their general practitioner and explain that they need to go through the algorithm that has been set by pain societies before considering cannabis as a treatment option.
Once they have gone through the standard process for pain management, many patients are usually satisfied and don't even need medical cannabis.

What problems do you see with medical cannabis?
One of the major obstacles to using medical cannabis right now is that every physician seems to have his or her own personal opinion. There is no medical regulatory authority in Canada that recognizes medical cannabis right now. So, many doctors who prescribe it are like pioneers and rebels out there, in a manner of speaking. I'm a very conservative medical cannabis prescriber.

One reason for this is the lack of guidelines. Right now, they do not tell us how to properly dose and choose which patients will benefit the most from medical cannabis. Now that Sandoz Canada has teamed up with a cannabis producer, they can provide the background to make these products a lot more accessible for physicians who want precise dosages. And I think this is very good news for pharmacists as well. If Sandoz Canada can make precise formulations, pharmacists will want to work with them and so will physicians.

Based on your experience with your patients, does access to medical cannabis improve lives?
Oh, absolutely. There is no doubt in my mind. But there is a danger here of using personal experiences with your patients as the basis for general recommendations for medical cannabis. We simply need more than just empirical evidence. But I believe it is already extremely helpful for certain people in certain circumstances. I've had patients telling me – and this is a recurring theme in many patients with chronic conditions – that medical cannabis has had a really positive impact on their quality of life. The one comment I keep hearing is ‘I have my life back.’

“I’m a very conservative medical cannabis prescriber because of the lack of guidelines for physicians.”

I think there are probably thousands of people right now in Canada who would benefit from medical cannabis but can’t access it because their physicians are either too afraid or skeptical. Also, patients who are really sick, elderly patients or people with difficulty finding someone to advocate for their condition will have access problems. On the other hand, there are probably thousands of people who shouldn’t be getting medical cannabis because there are better treatment options available for them. This is a very strange situation we're in. But things may be about to change. ■
Illuminating the path for biosimilars: an Italian access story

For years, many patients in Italy had difficulties accessing modern biologic therapies. The lack of clear policies limited the use of biosimilars as cost-effective alternatives. Now, thanks to the persistent efforts of advocates across political and industrial sectors, these state-of-the-art therapies are available for a larger number of patients. A model story about how legislation affects health outcomes.

When looking back at the negotiation process for a new law on biosimilar medicines in Italy, Michele Uda and Manlio Florenzano use these words to describe it: “Difficult,” “tough,” but “ultimately successful.” For two years, Uda – director of the Italian Generic and Biosimilar Italian Industry Body (“Assogenerici”) – and Florenzano – coordinator of the Italian Biosimilar Group (IBG, the Alliance of Biosimilar Producers within Assogenerici) and Country Head of Sandoz Italy – met with politicians and representatives of medical and other pharma associations within a working table organized by the Italian Industry Minister. Their common goal was to improve access to biologic treatment options in the Italian market and support the development of new policies regulating their use. Although this sounds like a bureaucratic task, it was, indeed, a significant change that would determine the quality of many patients’ lives. “Two lights were illuminating our path – the need to grant better access for patients and the need to make the market more sustainable,” Uda says. To understand what was at stake, we need to look back several decades.

The advent of biologic medicines in the early ’80s was a breakthrough in the treatment of previously difficult to treat diseases including arthritis, anemia, multiple sclerosis and certain types of cancer. For the first time, patients could receive therapies based on disease-associated proteins that significantly improved health outcomes. However, the complex process of producing biologics, which involves living cell cultures, makes them expensive, which resulted in limited access to these treatments. But when patents for biologics expired, a second revolution followed with the development of biosimilars. In 2006, the first biosimilar was introduced in Europe by Sandoz – and it offered a more affordable biologic treatment option. Just like their reference medicines, biosimilars are produced in living cells. And like the reference biologics, biosimilars have to undergo several tests to prove they have the same clinical benefits and match their reference medicine on quality, safety and efficacy.
Patients in Italy now benefit from better access to biologic treatment options because of a new law on biosimilars.
For this purpose, the European Medicines Agency developed a dedicated regulatory pathway for biosimilars, which is recognized globally as a gold standard. For more than a decade, the framework has been installed in many countries worldwide and almost everywhere in the European Union – and subsequently, biosimilars have proven their positive effect on patients’ outcomes and healthcare sustainability.

These outcomes were also shown in a recent report by the European Commission. The market entry of biosimilars can create healthy competition and therefore healthcare savings, as well as a significant increase in uptake, with a volume gain of more than 50% in some cases, even doubling in others. So, with access to biosimilars, the cost of biologic therapies decreases while the number of patients who can receive those treatments increases. This results in positive effects on a healthcare system’s sustainability. In 2016, IMS Health (now IQVIA Institute for Human Data Science) estimated that biosimilars could lead to savings up to EUR 100 billion by 2020 in the United States and the five major countries in the European Union, which opens up opportunities to “free up resources for investment in new areas and bring relief to pressured healthcare budgets.”

**Fighting “undertreatment”**

While patients throughout Europe have benefitted from these innovative treatment options, patients in Italy didn’t have sufficient access. “Although biosimilars were available in our country,” Manlio Florenzano adds, “physicians rarely used them for therapy. Too often, healthcare professionals, patients and politicians didn’t fully accept that, just like the reference biologic, biosimilars are state-of-the-art therapies. As a result, from about 2006 onward, “biosimilars accounted for only 10% of the market volumes,” he explains. “The possibilities were there, but still patients remained ‘undertreated’.” A study conducted by Ernst & Young (EY) supported him: It also showed that up to 300,000 Italian patients suffering from cancer or autoimmune diseases, such as rheumatoid arthritis, did not have access to leading biologic therapies. Lack of confidence among doctors and patients with these therapies, and the scarcity of specialized biologic centers, are potential explanations for this “undertreatment” cited by the EY analysts. As well, they cited the high cost of biologics as a possible cause. For these reasons, biosimilars represented an opportunity to fill this treatment gap.

The key principles – and outcomes – of the Italian law on biosimilars

In December 2016, a new law on biosimilars was approved in Italy to improve access to biosimilar medicine in order to increase sustainability of the healthcare system and improve patients’ access to biologic therapies. The key principles of the law are:

- Biosimilars and reference medicines have the same therapeutic outcome.
- There is no automatic substitution between the reference biologic and its biosimilar, or between biosimilars. Once a biosimilar is available on the market (and wins the tender), a physician must decide whether to switch to the new treatment option or not.
- If there are more than three competitors of the same biologic substance, there must be a multi-winner tender model. Patients can be treated with any one of the chosen brands, thus ensuring that there are treatment choices for physicians and patients.
- Physicians play a central role. They are free to choose the substance that they believe is the best for their patients.
- When the patent of a reference biologic has run out and a new biosimilar is available, authorities must accept suitable new biosimilars within 60 days. This provides sustainability to the companies entering the market and ensures a continuously growing number of treatment options for patients.

The key principles – and outcomes – of the Italian law on biosimilars

Fighting “undertreatment”

The EY report also led to another question: Why was the situation in Italy worse than in other countries? For Michele Uda, the main reason was a lack of official policy for the use of biosimilars. “The Italian market remained very fragmented and very limited in terms of accessibility of biosimilars,” he explains. This unstable situation had negative impacts for Italian patients and healthcare professionals, but also for producers of biosimilars who sought to offer these novel treatment options for patients.

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options. Insufficient and fragmented regulation had made it difficult for biosimilars to be optimally utilized. In addition, says Uda, therapeutic equivalence – a scientific principle of the same clinical effect and safety profile between a biosimilar and a biologic that is already on the market based on the marketing authorization process – was not formally accepted. As a result, “biosimilars were used almost exclusively for the treatment of patients who had not received any biological therapy before,” Uda explains. “There was simply no guidance for using biosimilars in the other patient groups who were in the middle of their therapy.”

But even when a biosimilar became available, doctors and patients couldn’t access it for a long time. Due to a restrictive tender (contract offer to supply the market) process, “biosimilar producing companies had to wait more than six months after approval of their products in order to enter the market,” Uda continues. And once on the market, regional authorities tried to urge physicians to use the lowest-priced biosimilar medicines, he explains. However, this attempt backfired. “The price pressure thus created reduced the acceptance of biosimilars in general by healthcare professionals. As a result, biosimilars weren’t a treatment option for doctors, and, therefore, patients didn’t have access to these therapies. For the manufacturers, it was like jumping into a pool without water.”

Negotiation, mediation and communication
Something needed to be done to clear up all the misconceptions and insecurities in order to improve access to more treatment options. For Florenzano, the need for an official regulation of the biosimilar market in Italy was a crucial step in order to improve the situation. In 2014, he and his colleague Enrica Tornielli, Head of Pharmaceutical Affairs of Sandoz Italy, felt compelled to tackle what turned out to be a long process. “We started working with all stakeholders to define a legislative framework that would open access to biosimilars and provide the opportunity to bring benefits to patients. Doctors, patients, financial regulators and industrial associations’ points of view were taken into consideration to try to find a common solution,” Florenzano explains.

Together with Uda, they led frequent deliberations with different stakeholders and prepared briefings for members of the Italian parliament. “It was extremely important for elected officials to understand the benefits that biosimilars could bring to patients’ access to biological therapies and to the healthcare system in Italy,” explains Florenzano. “Every argument was based on summaries of scientific data.”

Overall, their passion and strategy worked hand in hand to contribute broad expertise to the legislative process. “First, we led a wide negotiation among the pharma associations to find a common baseline. After reaching consensus, we presented our shared proposal to policy bodies for consideration,” Florenzano says.

Reaching the goal
At the end of all these steps, a new law on biosimilars was approved in December 2016. The focus of this law is to define a standardized framework to regulate the biosimilars market and to ensure open competition that could improve access to much-needed treatment options for patients, either to existing biosimilars or to future therapies. At the same time, the law gives a standardized framework to regulate this market and ensure competition. “It strengthens the role of prescribing physicians, while introducing framework agreements that ensure physicians can choose between different products,” Florenzano explains.

Uda also welcomes the fact that the new regulations support healthcare professionals with their treatment decisions. While it is still too early for a complete assessment of all benefits, initial results are encouraging. “There is now a much better acceptance of biosimilars in Italy than back in 2006 when the first products entered the market,” Florenzano says. Initial data from the Italian Biosimilar Group in March 2018 revealed an increasing trend in biosimilars uptake across Italy, with annual growth of 74% between 2016 and 2017, and reaching 19% of market share. This means that physicians are starting to use biosimilars as a treatment option more often to improve their patients’ lives. Uda summarizes, “Today, we can treat patients earlier, and we can treat more patients than before.” Adds Florenzano, “These results made the long path of negotiation worth it.”
In aging societies, value added medicines might bring benefits to patients and healthcare systems because they are designed to enhance existing generic medicines.
“Our role is to understand patients’ needs and use this knowledge to improve our medicines to better meet those needs.”

Nick Warwick, Chief Medical Officer at Sandoz
Value added medicines (VAMs) are an increasingly significant way to provide broader access to innovative treatment options. VAMs are generic medicines that have been enhanced in a variety of ways to better address patients’ needs – and improve patients’ lives.

A crying toddler, sick with pneumonia, needs a dose of antibiotics. His mother has the medication – but first she has to prepare it. This means adding water to a gritty-tasting powder in a bottle, then extracting the liquid mixture at a precise amount into a syringe. Now she has to try to get the liquid into the mouth of the feverish, cranky child. Already uncomfortable, the child jerks away from the syringe coming at him – and the antibiotic ends up spilled all over his shirt. Now imagine the benefit for the young patient, and the relief for his mother, when this medicine is available as a small, quickly dissolving tablet that can be placed under the boy’s tongue. A user-friendly formula like this is one example of value added medicines, or VAMs.

Value added medicines, according to Medicines for Europe – the official trade association for the European generic, biosimilar and value added pharmaceutical industries – are defined as “medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers.” Because VAMs are based on known molecules, the basic ingredient is already there. To use an analogy, you could compare the known molecule – a generic medicine – to a bicycle. Then think of a VAM like a bike equipped with a small electric motor. On an e-bike, riders can go faster and travel longer distances with less effort. Or, parts of the bike can be added or replaced to make it more comfortable, convertible or safer. Similarly, medicines can be “upgraded” in different ways – to create tailored therapies for patients.

Reformulation, combination and repositioning
For a normal bicycle, a small motor surely is an upgrade. This means the rider will struggle less to go up a hill, for example, so he is more likely to continue. Similarly, in medicines, changes in dosage, strength, release characteristics or mode of administration can make it easier for patients to take them. Making a change like one of these is known as reformulation, and it can be done with established generic products. With the example of treating a sick child, a powder antibiotic requiring reconstitution can be converted into tablets that dissolve in the mouth. Not only does that reformulation make the medicine easier for the child to receive, but it also means that reconstitution is not necessary, and, because the dissolvable tablet is more stable, refrigeration is not needed. These latter factors are especially important when insufficient access to clean water and refrigeration can hinder the
Experts constantly look for ways to make existing medicines better in terms of efficacy, safety and convenience.
Another way to add value to existing medicines is by combining multiple medicines into one pill. The approach of combining can be especially important in cases where people need to take multiple medicines several times a day. Here, there is a risk that patients neglect to take them all or forget a dose. However, when two medications are combined (whether, for example, in tablet or inhaler form), patients usually find it easier to adhere to their treatment. As an example, patients with asthma and chronic obstructive pulmonary disease (COPD) tend to have low adherence to treatment, and this correlates with a higher risk of hospitalization. Ready-to-use combination inhalers help them continue their treatment regimen and can greatly improve their health and quality of life.

Increasingly, technology is also helping patients stick with their therapies. New and exciting ways of combining medicines and medical devices – such as digital apps or digital therapeutics – are on the rise. For instance, in the case of antidepressants, the medicine can be supplemented with an app delivering cognitive behavioral therapy. Such combinations can make the overall therapy more effective.

In addition to reformulating and combining treatments, new therapy options open when a medicine
that was developed for one condition can be used to treat another. This approach is known as repositioning. Repositioning entails either retrieving existing data, or generating new data, to support the use of a drug for a new indication or in a new treatment population – and it is an attractive alternative to the lengthy and expensive process of developing new medicines. Someone who can speak to the great possibilities of repositioning is Nick Warwick, Chief Medical Officer at Sandoz, and part of a team responsible for the development of value added medicines. “I am very excited about the possibilities that utilizing big data, including real world evidence, can bring in the area of repurposing medicines. If we can avoid exposing patients to unnecessary clinical trials, and take a fresh look at the data that we have, then this has got to be a great thing.”

Adding value – receiving benefits

It is not only current patients who benefit from these new developments. By creating VAMs, existing medicines can be made safer for future patients and less likely to cause adverse effects. On another level, VAMs enable the development of safer ways to administer these medicines, so physicians lower the potential for accidents not only for patients but themselves. This risk is particularly relevant when physicians administer oncology treatments. Frequently, healthcare professionals need to reconstitute freezedried powders in vials before they can give them to patients. During this multiple-step process, the risk of a needle injury, or the contents squirting out of the vial, is high. Reformulating existing medicines to provide ready-to-use chemotherapy saves time, reduces the risk of injuries and simplifies medicine handling.

The ease and convenience of handling medicine also plays a lifesaving role when it comes to antibiotics. Worldwide, some 700,000 deaths per year can be attributed to antibiotic-resistant bacteria, a growing global health threat. One reason for this development is insufficient compliance with a doctor's prescription. To be effective, patients need to take the full course – until the package is empty. When patients abandon their treatment midway, it can be compared to going only half the distance of a planned bike tour. The rider is left in the middle of nowhere – not yet at his destination, but with resources significantly depleted. Similarly, if patients do not take their medicine as prescribed, the level of antibiotics in the body is not sufficient to continue inhibiting bacteria. Thus, resistant strains can develop more easily. But when antibiotics are easy to use, such as through reformulation, patients take them more consistently. This way, therapy is likely to be more effective, and collectively, this is also likely to have a positive impact on reducing global bacterial resistance.

Offering a strategy against antimicrobial resistance is just one way that VAMs can support healthcare systems, says Warwick. Because VAMs are based on existing generic products, they can offer a cost-effective alternative to certain treatments while, at the same time, provide access to high-quality therapy for patients. Although the cycle of VAM development is still in the early stages, Warwick is convinced of their potential. “Value added medicines allow us to focus on the needs of individual patients and enable a more patient-centric and personalized therapeutic approach. I believe that VAMs are one way to improve access to healthcare for patients, now and in the future.” (See Nick Warwick's perspective on the next page.)
Perspective

How VAMs increase access to healthcare

Addressing unmet medical needs

While not many people may be familiar with the term ‘value added medicines,’ patients are familiar with problems they have when they use existing medicines. This is why I usually describe a VAM as a better version of the best available existing generic medicine – for example, by making it easier and less complicated to take, by changing the side effect profile or by combining two effective medicines into one. Another example is when a generic medicine used for one medical condition can be shown – through generation of appropriate data – to also benefit patients with a separate, unrelated medical condition (so-called ‘repurposing’ or ‘repositioning’). But to achieve these things, we first have to really understand patients’ needs and use this knowledge to best improve our products, so these needs can be met. This is the underlying concept of value added medicine development.

Discovering candidates for enhancement

There are several ways we can discover new candidates for value added medicines. One way is to view our existing portfolio of products with an external mindset. We typically do that through advisory boards with doctors, pharmacists and patient representatives. We listen to the problems they are having with their current medication and to their ideas for improving the product.

Another very exciting way to identify potential candidates for VAMs is by gaining an in-depth understanding of how a particular medicine works to benefit patients with a specific condition – and then looking to see if that therapy could be extended to treat patients with other conditions. Here, we can increasingly use big data and digital technologies, including artificial intelligence and machine learning, to identify ways of repurposing drugs from treating patients with one disease type to another. This can be done by sifting through large amounts of data like patient records, clinical trial...
data and publications. Other data sources – from publicly available and proprietary databases, conference reports, abstracts and the like – can also be reviewed to recognize patterns of a medicine’s characteristics and usage.

We also receive fantastic ideas from our community of Sandoz associates and their families, among which are scientists, technicians, researchers and other trained healthcare professionals.

Developing VAMs requires a hybrid approach

Once we have an idea for an enhanced generic medicine, our Product Development team sets out to translate it into a drug ready for patients’ usage. The efforts to do that sit somewhere between developing a ‘standard’ generic product and developing ‘new chemical entity’ medicines. Developing a typical generic medicine usually takes about three to four years and an investment of single-figure millions of dollars. Conversely, it takes many years and billions of dollars of investments to develop completely new pharmaceuticals. Value added medicines sit somewhere in-between, which means there is still a substantial amount of research and investment involved.

When developing a VAM, the amount of data we need to generate is very different to that required for standard generic products – this is because of the differentiating features of a VAM as compared to a standard generic. For example, we will need to conduct clinical studies to better understand how the body handles the VAM. Plus, of course, we’ll also need to understand the effect of the drug on the body - either as part of healthy volunteer studies, or studies in patients, and this may entail large Phase III trials. We may also need to look at doing patient experience studies in the post-marketing setting, and studies especially designed to characterize the ‘value added’ nature of the drug. Our development approach needs to be specifically tailored for each VAM, and the type of approach we take very much depends on what change or modification is needed to add value to a medicine.

Reducing waste and inefficiency

For therapies to be effective, patients typically need to take their medication at a certain dosage, sometimes at the exact same time of a day, and continue to do so as long as prescribed. This is especially important for patients with chronic conditions. However, 50% of patients fail to take their medication as prescribed, according to WHO. For me, this number is shocking. At the same time, it motivates me in my work in the VAMs field because I believe that anything we can do to improve existing generic products to increase treatment compliance will be good for patients and our society at large.

Addressing universal healthcare

By developing enhanced generic (value added) medicines, I believe we also can help address some of the key barriers to universal healthcare coverage, a concept well-established and actively promoted by WHO. I believe it is a fundamental right that we get healthcare at a cost that is not going to cause significant or undue financial hardship. The top three leading causes of global healthcare inefficiency include underuse of generic products, use of substandard medicines (with associated quality issues) and inappropriate and ineffective use of medicines. I believe VAMs can really make a difference in this area. As indicated by an analysis from the IQVIA Institute for Human Data Science, responsible use of medicines could help save almost USD 500 billion worldwide. This would allow a more efficient use of healthcare budgets, helping countries in the effort to provide universal access to medicines without endangering financial sustainability. For me, this makes VAM development all the more relevant, and rewarding.
On September 19, 2017, a satellite captured this picture of Hurricanes Maria and Jose moving through the eastern Caribbean Sea.
“On average each year, 11 tropical storms, 6 of which become hurricanes, develop in the Atlantic Ocean, Caribbean Sea or Gulf of Mexico. Their potential for loss of life and destruction of property is tremendous.”

*Hurricanes... Unleashing Nature’s Fury*, informational booklet by the US National Oceanic and Atmospheric Administration
Weeks and even months after Hurricane Maria hit Puerto Rico, people were still suffering from crippled infrastructure.
After the storm – Accessing medicine after Hurricane Maria

Puerto Rico’s infrastructure was severely damaged by a hurricane in September 2017. Non-profit Americares arrived immediately after the disaster to provide access to medicines and medical care. Supported by Sandoz, they’ve been there ever since.
Apocalyptic” was the word officials and reporters used to describe the devastation. Buildings and roads were blown apart. Power lines dangled onto roads. Shards of wood, once walls, and splinters of glass, once windows, were left, along with papers, photographs, clothing and toys, all strewn into a wet pulp. This was the state of Puerto Rico after a single storm. That storm was Hurricane Maria, with winds of more than 155 miles (250 km) per hour when it landed on September 20, 2017. Earlier in the month, the island had already lost power after Hurricane Irma. With Maria, whether in a city like Ponce or a remote island like Vieques, almost all of Puerto Rico was severely damaged, if not destroyed. This was the worst known disaster in the territory’s history.

What the hurricanes couldn’t destroy was the Puerto Rican people’s spirit to rebuild. But alongside rebuilding came day-to-day, or even moment-to-moment, survival. In the days, weeks and months that followed, many residents did not survive due to Hurricane Maria’s direct and indirect health effects, with the latter being the consequence of a massive access breakdown. Because the storm damaged infrastructure, many Puerto Ricans found themselves without medicines and medical care; as time went on, chronic or usually treatable ailments became severe, and even deadly. Though the hurricane’s immediate death toll was reported as 64 people, there may have been at least 1,000 deaths directly or indirectly related to Hurricane Maria. As horrific as these figures are, the number might have been significantly higher without the efforts of people like Raul Pineda.

Now overseeing the Americares team in Puerto Rico, Pineda is the Latin America Recovery Director at Americares, an international health-focused relief and development organization that responds to people affected by poverty or disaster with health programs, medicine and medical supplies. On September 20th, as Maria hit Puerto Rico, Pineda and his team were already preparing to deploy; as in all disasters Americares responds to, they monitored the situation as soon as it became a potential emergency. Thus, when the storm hit, they were ready to swing in to action to bring people and supplies to the island. When the team arrived, they discovered the devastation was massive. “There was no means of communication there: phone lines and mobile lines were down. There was no electricity, no water,” Pineda says.

As in all emergencies, the help starts with a situational assessment, so work can be prioritized. But without even the most minimal infrastructure, how did Pineda and his team proceed? “Person-to-person information,” Pineda explains. “We travelled as much as we could across the island, whether on foot, by jeep or helicopter, personally gathering information. Then we could assess what the people needed, what could be done and where we could help.”

Help was needed everywhere – and it would be needed for an indefinite period. The first step was for Pineda to organize medical supplies to be delivered to affected health facilities. But finding a safe, climate-controlled location to store medicine during the blackout was a challenge. “So we established key contacts in Ponce, where there was a warehouse with enough fuel supply to run the facility for the first month. These contacts helped us get our medicine and medical supplies in position. Then we could deploy medical teams across the island, even to isolated areas.”

“They were survivors themselves – they had lost their homes, even members of their families. And they were out there helping their neighbors.”

Raul Pineda, Latin America Recovery Director at Americares
With the majority of Puerto Rico severely damaged, access to medicine has had to compete with access to food, water and shelter.
Making personal connections was also something that aided the Americares team in their journeys around Puerto Rico, explains Pineda. “We have seen so many heroic examples, even people who had never experienced an emergency, or one of this scale. Local people. People who are normally, for example, clerks. But once this emergency came, they were just helping others: clearing roads, transporting people, trying to be a voice of the people who could not speak up.”

The will to survive
These were not the only good deeds. Pineda and his team found that even people who themselves needed to get to the nearest health facility managed to put themselves into action in any way they could: “They were even clearing the roads themselves, to let us know they were there and needed to be evacuated. Without those persons...” Pineda pauses. “I mean, more people would have died. They were survivors themselves – they had lost their homes, even members of their families. And they were out there helping their neighbors.”

This level of effort was also necessary, Pineda continues. “Most of the roads in the countryside were closed. The dimensions of the disaster were so big that the capacity of agencies to clear roads was overwhelmed. So many communities cleared roads on their own – which allowed us to find them, and the patients that were house-bound, or out of medicines.” In addition to immediate health emergencies, people with chronic conditions like diabetes or hypertension found that otherwise manageable conditions became emergencies. “The pharmacies were closed, the doctors’ offices were closed,” explains Pineda. “And people were not keeping enough medical supplies; no more than two to three weeks’ worth. So we were helping them through mobile medical clinics.”

In one example, in the isolated, eastern island-municipality of Vieques, such a medicine shortage became a life-threatening situation. “We were able to reach Vieques and get our medical experts there. In some cases we found, people needed to be flown to the main island for medical treatment. During one of these medical consultations, we identified a patient who had high blood pressure. Normal blood pressure is considered 120 over 80, but this man was almost 300 over 140. He was on the verge of having a heart attack.

After Hurricane Maria hit Puerto Rico, non-profit Americares, which is supported by Sandoz, began providing medical care.
We were able to bring him to an emergency site, and then the military flew him to the main island for treatment. And that is just one example of a chronic patient, in need, who didn’t have his medicines for a long time.”

Supporting the first responders
Pineda and Americares’ efforts have been supported by Sandoz since 1986, providing the organization with antibiotics and other essential medicines. Since 2016, the level of donated medicines to Americares has reached a value of USD ten million annually. Today, these medicines include over 25 products for treatment of infections, cardiovascular conditions, eyecare, skin conditions and musculoskeletal pain. According to Leslie Pott, Vice President Communications, Sandoz US and a member of the Novartis Foundation, “We’re living in communities in Puerto Rico as a global organization. We have friends or even family in these places – personal connections. So when Americares goes to places like Puerto Rico with our medicines, that makes us proud.” But supporting Americares is about more than just company pride for Pott; it’s about how Americares serves communities in need: “Through their reach, thoughtfulness in product selection, their approach and diligence – they are very careful with resources and so extremely effective in helping people.” In turn, Pineda and the Americares team are also grateful for the contributions of partners like Sandoz. Americares’ Donna Porstner relates, “With such frequency and intensity of disasters, we have to have a roster of professionals, and supplies, ready to deploy.” Adds Randy Weiss, Americares Senior Director of Corporate Relations, “We’d be unable to do our work without our partners.”

Even now, a year after Maria, there remains much work to do, and there will be for the foreseeable future. Critical infrastructure, such as electricity, is not yet fully restored. Puerto Rico not only has to repair past damage, but it also must prepare for the future. As just one example, Americares is hosting disaster preparedness workshops for health workers in Puerto Rico serving the most vulnerable residents. Pre-positioning medicines in strategic areas of the island to ensure access in catastrophic situations is also a priority going forward, he explains. “People are more aware after Maria about being prepared at all times and revising those plans.” Pineda also explains that both for residents and first responders, support for post-traumatic stress is needed, and is being offered, as a key component of mental health, so everyone can be fully healthy – and ready.

This preparation is necessary. In 2018, the US National Oceanic and Atmospheric Administration (NOAA) again foresaw a “near or above-normal hurricane season.” Pineda remains calm in the face of such news. “The people of Puerto Rico are vulnerable to such extreme weather conditions, but they are helping each other. This level of dedication is indescribable,” he says of the island.

As of the summer of 2018, major US federal organizations such as FEMA have scaled down operations in Puerto Rico, and the US Army Corps of Engineers has left. But Pineda explains that as long as access to medicines is needed in Puerto Rico, whether because of Hurricane Maria or any other event, “Americares will be working there, even if it takes years.” Thanks to their work, and the support of their partners, programs are in place to help Puerto Ricans prepare – both physically and mentally – for upcoming hurricane seasons. Says Pineda, with complete certainty, “If anything happens, we will be ready.”
Ambassador for access

Dr. Hua Yue
specializes in endocrine and metabolic diseases at the Department of Osteoporosis and Osteopathy, Shanghai No. 6 People’s Hospital. Her wish to improve her knowledge keeps her in the hospital even after the night shift.

“Medical treatment means dealing with people from different cultures and backgrounds.”

What access problem would you like to solve?
In China, the public knows little about osteopathy, a non-invasive therapy that treats mobility problems by moving and massaging muscles and joints. So I devote myself to helping patients understand how this treatment can help relieve pain and help them live fuller lives. Also, patients have different cultural backgrounds, so I think adapting our advice is a key to getting them to accept treatment.

How does your work help to improve access?
By offering my services as a doctor, I can alleviate patients’ misery with my own hands. Having passion for this occupation pushes me to keep learning and to be an expert in my field. This is why in my private time, I keep myself busy with scientific research. I am helping to improve medical services in my country. This is what I can do for mankind. If I wasn’t a doctor, I don’t know what else I would do.

What motivates you in your job?
Because I was very weak as a child and medical treatment was hard to find, my parents had to ask all over town for help. Due to the experiences of searching and begging, they always thought curing diseases is something very difficult. So I believe it is my duty to relieve the mental and physical suffering of patients – and lighten the families’ burden every single day.
The access factor

Light and health

Globally

1.5 million

Disability-adjusted life years (DALYs) are lost globally every year due to excessive UV radiation exposure. According to WHO, “one DALY can be thought of as one lost year of ‘healthy’ life.”

0.1%

This equals 0.1% of the total global burden of disease.

3.3 billion

However, zero exposure to sunlight has even worse effects on health. According to WHO model calculations, a loss of 3.3 billion DALYs is prevented due to beneficial effects of UV radiation and associated vitamin D production.

Light-related diseases

9 diseases

are clearly associated with UV radiation exposure, most notably skin cancer and eye cataracts.

UV radiation exposure is necessary for the production of vitamin D – the "sun vitamin” – essential for bone health and preventing autoimmune and other chronic diseases.

History

For the ancient Greeks and Romans, Apollo, the god of sun, made his way across the sky in his fiery chariot to bring life-giving light to the planet. Apollo was also the god of medicine and healing – but he could bring sickness as well as cures. Today’s scientists have come to a similar recognition that exposure to the UV radiation in sunlight has both beneficial and negative effects on human health.

In 2017, the Nobel Prize for Medicine was awarded to a team of researchers for their discoveries of molecular mechanisms controlling the circadian rhythm, the biological clock that helps organisms anticipate and adapt to the rising and setting of the sun.

Access to light

1 billion

people worldwide are vitamin D deficient or insufficient.

15–20 min.

of sunshine per day on 40% of the body's skin surface can prevent vitamin D deficiency.

Sources:

http://www.who.int/uv/resources/archives/fs305/en/
http://apps.who.int/iris/bitstream/handle/10665/43565/9241594403_eng.pdf
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D

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D

UV radiation exposure is necessary for the production of vitamin D – the "sun vitamin” – essential for bone health and preventing autoimmune and other chronic diseases.
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