Committee: World Health Organization (WHO)

Issue: Promoting access to medical innovation by creating a new medical research landscape

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Position: Deputy President

PERSONAL INTRODUCTION

Dear delegates,

My name is Celia Kalogeropoulou, I am a student in Pierce - The American College of Greece in 10th grade and it is my utmost honor to be serving as one of the Deputy Presidents of the World Health Organization (WHO) in the 5th annual ACGMUN. Having been an active member in MUN conferences, I can undoubtedly say that they provide an amazing opportunity for all participants to become familiar with ongoing issues of the modern world, as well as meet new people and form long-lasting relationships.

This year's agenda includes four important and heated topics that the world has to tackle. The topic that this study guide will be covering is "Promoting access to medical innovation by creating a new medical research landscape", which is a rather important one and affects policies worldwide.

The purpose of this study guide is to facilitate your research, by making you aware of the key terms, background information and foundations of this topic. Nevertheless, you should not only rely on this guide, but also do your own research, in order to be able to defend your country's policy sufficiently and participate actively in the process. I genuinely anticipate hearing your views and further discussions upon the matter!

Should you have any questions, concerns or need any kind of further clarification, do not hesitate to contact me at: Vasiliki.Kalogeropoulou@acg.edu

I am truly looking forward to meeting you all!!
Kind regards and stay safe,
Celia Kalogeropoulou.

TOPIC INTRODUCTION

Medical innovation includes any health advancements, no matter how basic or complicated, that contribute to better health outcomes and patient experiences. Enhanced systems used by healthcare professionals, new clinical services, and new products to assist patients, are all examples of innovation in the health industry. Medical innovation has always been a vital and integral part of human existence, with signs of medical innovation being around since 3300 BC, when early doctors of the Stone Age used herbal medicine in order to reduce pain. Aiming to cure diseases and prevent their spread, while also helping monitor their possible effects, medical innovation techniques contribute to detecting and diagnosing symptoms faster. In our days, the model of medical innovation has been significantly transformed, being mainly dependent on medical research. Due to medical innovation, diseases that were once considered fatal, such as AIDS/HIV, can be now turned into manageable long-term ailments.

However, today's medical research landscape is need-based as well as market-based, which fails to address the demand for new medical products concerning overlooked conditions, such as tropical diseases, which mostly affect Less Economically Developed Countries (LEDCs). In the status quo, one third of our planet's population does not have facile access to medical innovation. In addition, the ethical dimension of medical research includes strict regulation and framework, liability difficulties, and high expenses. Even though medical innovation is, in most cases, not expensive to be effected, it can be rather costly to research. Thus, the process towards the creation of medical innovations is complex, time consuming and not easily accessible. Creating a new medical research landscape will help achieve Decent Work and Economic Growth, which is this year's theme, since it revolves around the three basic values of "Discovery, Development and Delivery", that will be given equal attention, ensuring easier access to medical innovation. Consequently, it is crucial to encourage the creation of a new medical research landscape since innovation that is not accessible is wasteful.

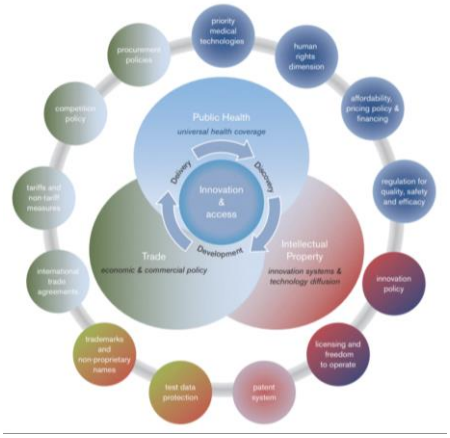

Figure 1: Key areas of law and policy for innovation and access [1]

DEFINITION OF KEY TERMS

Artificial Intelligence

"AI is a wide-ranging branch of computer science concerned with building smart machines capable of performing tasks that typically require human intelligence."[2]

Intellectual property (IP)

Intellectual Property (IP) systems work by granting restricted rights to safeguard protected content from specific defined third-party uses, and "refer to creations of the mind, such as innovations." [3]

Medical Research

"Medical research involves research in a wide range of fields, such as biology, chemistry, pharmacology and toxicology with the goal of developing new medicines or medical procedures or improving the application of those already available. It can be viewed as encompassing preclinical research (for example, in cellular systems and animal models) and clinical research (for example, clinical trials)."[4]

[1] "Promoting Access to Medical Innovation." *WIPO - World Intellectual Property Organization*, www.wipo.int/wipo_magazine/en/2013/05/article_0002.html.
[2] Mehta, Reshmi. "UNINFORMED SEARCH ALGORITHMS." *Medium*, 26 Aug. 2020, https://medium.com/analytics-vidhya/uninformed-search-algorithms-c87febbd0bb7
[3] "What is Intellectual Property?" *WIPO - World Intellectual Property Organization*, https://www.wipo.int/publications/en/details.jsp?id=4528#:~:text=Intellectual%20property%20(IP)%20refers%20to,trademarks%20and%20other%20commercial%20signs
[4] "Medical Research." *Nature*, 26 Nov. 2021, www.nature.com/subjects/medical-research

Medical Innovation

Medical innovation is the process of coming up with new medical concepts. In the world of medicine, innovation encompasses more than only the creation of new medications. It also entails the creation of technologies to help in the diagnosis, monitoring, and treatment of medical conditions, as well as improving existing business processes and models to better meet changing demands and expectations.

Patent

"A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application." [5]

Research landscape

"The research landscape is based on organizational analysis," which is the process of examining the growth, working condition, workforce, and functioning of a corporation or other sort of organization. "The concept is focused on finding a cohesive and consistent view of the main organizations and initiatives in some analyzed area of operations and analyzing chosen key aspects of them."[6]

BACKGROUND INFORMATION

Medical innovation

Medical innovation has revolutionized the way we provide and manage treatments, as well as the way we structure healthcare systems. Its accessibility is mainly based on the infrastructure, the services, and the workforce available in each country. Nevertheless, today's crisis concerning access to medicines and innovation is a global one, not only impacting less economically developed nations.

There are limitations imposed on the access of medical innovation due to modern medical research techniques. More specifically, medical research techniques are mainly revolved around conditions faced in more economically developed countries, leading to the increase of discriminatory phenomena. One of the most evident examples is the so-called 10/90 gap, where only a 10% of global health research disbursement is dedicated to topics that impact the poorest 90% of the world's

[5] "Patents." *WIPO - World Intellectual Property Organization*, www.wipo.int/patents/en/
[6] "What is Landscape Analysis? | RISCAPE." *Blogs at HelsinkiUni – University of Helsinki Blogging Platform, https://blogs.helsinki.fi/riscape-project/what-is-landscape-analysis/*

population, since nowadays the medical research landscape is both need-driven and market-driven. In 2001, the Treatments for Neglected Illnesses Working Organization, an independent group of specialists organized by MSF, presented findings demonstrating that just 1% of new drugs licensed between 1975 and 1999 were focused on neglected tropical diseases, which accounted for 12% of the worldwide disease burden. The study provided numerous recommendations, including investigating a new program for collaborative, not-for-profit medication development. It defines the issue, as a result of both market and governmental policy failings.

In this market-driven landscape, individuals will select from among the alternatives provided based on their expectations for cost, results, and quality, which is a key principle of market-driven improvements in health care delivery. These options are based on the idea that reliable information about health-care services is available, and that providers and plans are held accountable for the services they offer. Health services research may help influence decisions regarding clinical services, as well as the management and funding of health care, by providing knowledge about what works, when, and at what cost. As a result, one of the most urgent public policy issues of our day is finding the correct balance between health, trade, and intellectual property rules in order to sustain innovation and enable widespread access to life-saving technologies.

In collaboration with the international health community, the pharmaceutical industry plays a critical role in responding to defined global health priorities, developing much-needed innovative products, facilitating access to those products that already exist, and forging new partnerships to promote long-term, sustainable access to medicines. In the development of the Covid-19 vaccine, for instance, the researchers investigated the spike protein found on the surface of coronaviruses using their prototype coronavirus. Researchers used to try to include the spike protein into the vaccination. The vaccine would boost a person's immune system to defend them from a specific coronavirus after being administered. However, the scientists realized that producing vast quantities of a specific spike protein would take too long during a pandemic. Thus, they devised a method of introducing a spike protein into the organism. This innovative method involves injecting the spike protein's mRNA instructions into a person's muscle. The spike protein is then produced by the muscle cells, and then, the immune system then produces the necessary antibodies to defend the body. This process revealed how in a global crisis the pharmaceutical industry plays an important part when it comes to innovation and accessibility.

One of the most distinguishing qualities of the pharmaceutical sector is its constant innovation. New treatments have the potential to improve the quality of human life and possibly extend it. The business potential is enormous: by 2023, the global pharmaceutical market is anticipated to be worth $1.1 trillion. Thus, there is a lot of pressure to succeed. Pharmaceutical innovation, however, is far from a straightforward and predictable process. It follows a technology-push paradigm that is based on a winding route of scientific advances with uncertain timing and results. While technological expertise, decades of detailed research, and a deep grasp of unmet customer needs are all crucial, they may not be enough to ensure market success if the choice to commercialize is made outside the company.

All parties must act to improve access to medication, with each having their own duties and obligations. Scientific research, local governments, public health and regulatory agencies, foreign development agencies, philanthropists, multilateral organizations, and the nonprofit sector, including product development collaborations, are all included. Pharmaceutical corporations, who have the resources and expertise to develop and provide new medications on a large scale, have a duty to ensure that they are accessible to individuals of all socioeconomic backgrounds.

Difficulties on increasing accessibility on such technologies

Problems revolving around medical innovation accessibility are usually linked with the ability, or lack thereof, of individuals from low socioeconomic origins to afford research or receive new technologies. As a result, a great number of medicines and new technologies (including drugs, vaccinations, and diagnostics) are out of reach for the majority of the world's poor, especially in LEDC.

In addition, developing countries lack the necessary infrastructure to improve access to medicines. Most diagnostics aren't built to work in less-than-ideal laboratory circumstances, such as those found in impoverished nations, where there's no air conditioning, no reliable electricity, and no refrigerators to preserve samples and chemicals.

Faced with significant budget constraints, developing countries are constantly attempting to build contemporary health-care systems that include appropriate medical technology. However, medical research requires around $4, 13, and 20 million respectively, an amount of money that most countries cannot afford to dispense regularly. In 2000, a campaign organized by the World Health Organization (WHO) was launched, in an effort to raise awareness for drug-resistant tuberculosis (DR-TB) and decrease their cost, since those drugs can cost up to $14,000 for each

treatment course. Unfortunately, treatment for drug-resistant tuberculosis (DR-TB) is still challenging and expensive, with significant side effects and low cure rates. Thus, we are still fighting for medicines that are both effective and economical.

Developing countries must import a lot of technology due to their lack of development and lack of competence to make sensible decisions, which is not based on any incapability of the country in decision-making generally, but rather derives from weak policy structure and limited tradition of using research or policy analysis to implement action due to their economical state.

Another really important factor is ethics, especially in clinical trials. Clinical trials consist of studies made on humans or animals, aiming to test the innovation's efficacy and safety. When new medicines are first introduced, they are tested on a rather small number of volunteers or/and patients, making them less accessible to all who are in need. In order for clinical trials to be conducted, certain rules concerning the ethical aspect ought to be respected. Those include the benefit–risk ratio, where the participant's benefit is always meant to come first, the equal access to expected research benefits, the particular consideration for disadvantaged populations, ensuring the lack of discrimination and the protection of each participants' dignity.

Moreover, the ethical considerations surrounding the use of animals in medical research are numerous, making it even harder to conduct research. At the same time, most people believe that animals have moral status and that how we treat them should be based on ethical concerns, since animal welfare must be prioritized by researchers in order to reduce the possibility of suffering. Furthermore, religious medical ethics differs from secular medical ethics because of how it emphasizes the limitations of autonomous decision-making, of how it places a higher value on the experience of suffering, and draws on values and beliefs that are beyond experimental verification.

Medical innovation's effect on LEDCs

First and foremost, such an initiative would aid LEDCs by allowing governments to develop knowledge-based economies, as part of larger efforts to promote a vibrant research and development (R&D) environment, through the promotion of a strong health science industry that can help achieve development goals. In addition, it could lead to advances in health, social welfare, and poverty reduction. Reviewing the situation as it is right now, only a tiny percentage of global health research is focused on illnesses that solely impact Low to Middle Income Countries (LMIC) and Less Economically Developed Countries (LEDC). While the landscape has changed over the last three decades, many LMICs and LEDCs have been unable to acquire

adequate ability to generate their own national evidence base to directly drive policy and/or enhance the health of their populations.

Despite the fact that the number of citizens living in extreme poverty globally has declined over the last 30 years, poor living circumstances and rising populations contribute to the perpetuation of the poverty cycle. A large amount of the population in LEDCs live in squatter camps, and many of them lack basic necessities like sanitation, safe drinking water, and food security. As congested living spaces, stagnant water, lack of hygiene, and food deprivation contribute to respiratory infections, poor living circumstances affect entire communities. Access to medical innovation would allow more people to stay healthy and thus, engage in education and the economy, as living conditions would improve, and consequently would help in reducing inequality.

Artificial intelligence used in medical innovation

There has been a significant increase in the use of artificially intelligent computer systems in recent years in the medical field. Their use varies from diagnosing patients' conditions to filling prescriptions and even treating patients. Since technology keeps evolving, and becoming more and more accurate in its judgment, it is believed that in the near future, A.I. may replace human specialists.

The use of patents in medical research

Patents and other kinds of intellectual property protection systems are widely believed to be critical in promoting biopharmaceutical research. When a patent is obtained, the innovation becomes the inventor's property, which can be purchased, sold, rented, or hired just like any other type of property or business asset. Usually, different agencies, each functioning independently, are responsible for issuing patents and approving pharmaceutical goods for market entry.

MAJOR COUNTRIES AND ORGANIZATIONS INVOLVED

Switzerland

Switzerland is the first country globally in producing medical advances while providing the maximum freedom of choice in health care at the same time. More specifically, Switzerland has a large network of specialized experts, as well as well-equipped hospitals and clinics where the patients have the freedom to pick their own doctor and almost always have unlimited access to specialists. Since the adoption of the Swiss Federal Health Insurance Act of 1994 in 1996, that ensures that all residents of Switzerland must have health insurance, according to the law, all of Switzerland's 7.6 million people have had access to comprehensive medical care.

Netherlands

The Netherlands has achieved patient-centered care. They have succeeded in utilizing advanced science and technology in the medical field, which is easily accessed through private or public insurance. On a global scale, the Dutch medical care system is a high performer: the Commonwealth Fund placed the Netherlands third among affluent countries, while the Euro Health Consumer Index 2017 put it second. Adults are required to acquire basic insurance, and failing to do so might result in a fine. Employer contributions and taxes also contribute to the financing of healthcare in the Netherlands.

Germany

Germany is a country which has progressed significantly on the promotion of access to new treatments and the fast distribution of medical innovation to citizens. The German healthcare system, which dates back to the 1880s, is one of the world's oldest. Public and private health insurance are the two primary segments of the system. Moreover, the notion of solidarity underpins the German public health-care system. No matter their financial situation, all patients covered by public health insurance receive the same medical care. This is accomplished by a shared fund that is income-based and to which everyone pays.

Israel

Israel maintains a patient-centered health care approach. More specifically, Israel's hospitals have a forward-thinking attitude, continually developing with research and technology. Even though the cost of healthcare in Israel is much lower than in other nations, according to international standards, the quality of medical care is never compromised. The country has about 1,500 enterprises in the health care and biomedical sectors, with medical equipment and electronic health records accounting for nearly 70% of the total.

USA

Patients in the United States who are struggling financially may fall between the gaps as health technology advances. Those in the United States have more expensive access to newer drugs than patients in other countries. According to surveys, American prices are 20-40% more than those in eleven other wealthy countries. The American healthcare system is mainly private, and thus, inaccessible to those who cannot afford insurance. In order to improve the situation, the United States spends double as much on health than comparable countries, owing to increased payments to hospitals and physicians.

Thailand and Brazil

To combat excessive pricing for essential HIV drugs, the Thai government has overridden blocking patents to allow the development of inexpensive versions of efavirenz and lopinavir/ritonavir. Brazil has followed suit for efavirenz, by supporting a legal challenge to a patent for the HIV medicine tenofovir in order to make generics more affordable.

World Intellectual Property Organization (WIPO)

Through the creation of creative worldwide collaborations, WIPO's Re: Search initiative supports research and development strategies to help cure neglected tropical diseases (NTDs) such as malaria and tuberculosis. WIPO has also developed PATENTSCOPE, a website that promotes innovation by providing essential information on patents and licensing strategies.

World Health Organization (WHO)

In the World Health Organization's headquarters there is a group of professionals who willingly collaborate in order to promote and develop health innovation. They argue that health innovation's objective is to develop new or better health policies, products, systems and technology, as well as distribution methods, in order to enhance people's health, with a specific focus on the needs of vulnerable groups.

TIMELINE OF EVENTS

Date	Description of event
January 1, 1999	Access campaign is launched, with a focus on neglected diseases.
January 1, 2000	The World Health Organization (WHO) campaigns in order to reduce the price of drug-resistant TB (DR-TB) medicines and make them more accessible.
September 2, 2001	Report on the chronic crisis in research and development for neglected diseases, that revealed the situation in the status quo and aimed in providing an incentive in order to ameliorate the situation

November, 2001	The Doha Declaration addressed a number of IP-related concerns and notified the United Nations that IP should not prevent developing-country access to medicines.
January 1, 2005	India imposes laws that promote access to medical innovations.
January 1, 2006	Thai and Brazil government challenge patents in order to lower medical innovations' prices
June 22, 2011	Putting in place a new international framework to emphasize the significance of medical research and innovation
January 1, 2016	Significant drop in price for Hepatitis C medicines.
March 2, 2017	European Parliament resolution that revolved around increasing access to medications, particularly in underdeveloped countries, health research, and pharmaceutical items
January 1, 2019	The MSF Access Campaign continues to advocate for medical R&D, revolved around neglected conditions
April 2, 2020	Resolution asking for stronger scientific collaboration and worldwide coordination to battle the COVID-19 pandemic

RELEVANT UN RESOLUTIONS, TREATIES AND EVENTS

Essential Health and Biomedical R&D Treaty of 22 June 2011[7]

This Treaty aims to establish a new international framework in order to highlight the importance of medical research and development. The framework will be based "upon the fair and equitable sharing of the costs, access and benefits of research and development, incentives to invest in needs driven research and development

[7] "An Essential Health and Biomedical R&D Treaty", *WHO- World Health Organization*, https://www.who.int/phi/news/phi_1_joint_submission_en.pdf

consistent with human rights and with the goal of all sharing in the benefits of scientific advancement."

World Trade Organization (WTO)

The Doha Declaration on the TRIPs Agreement and Public Health, issued by the World Trade Organization in 2001, clarified a number of IP-related issues and informed the international community that IP should not limit access to medicines required in developing nations. The basic tenet of the Doha Declaration is the recognition that the rule of law and environmental sustainability are inextricably linked and mutually reinforcing.

Covid-19 related Resolution on April 2 2020

The United Nations General Assembly passed a resolution calling for increased scientific cooperation and global coordination to speed up the "rapid growth, production, and distribution of diagnostics, antibiotic medicines, and vaccines" necessary to combat the COVID-19 pandemic. The resolution also urged governments to immediately take actions to prevent speculation and excessive hoarding that may restrict access to safe, effective, and affordable vital medications, vaccines, protective equipment, and hospital equipment.

European Parliament resolution of 2 March 2017

This resolution revolved around EU options for improving access to medicines, especially pharmaceutical regulations in developing nations, health research, pharmaceutical products, intellectual property , EU competition strategies, medical services, the right to wellness and the cost of pharmaceuticals.

PREVIOUS ATTEMPTS TO SOLVE THE ISSUE

European Council

The "Building the future of health research" Proposal of the European Council focuses on the use of health data in the medical research process, which opens up a world of possibilities when working along with technological advancements. However, the use of health data as means of promoting medical innovation is currently untapped and underutilized. The aforementioned proposal suggests people-centered research to be conducted, in order to achieve maximal impact that will be assessed from a societal and economic perspective. This will complete the circle of research, innovation, and health care, allowing for input on new discoveries and innovation. However, this initiative is yet to be adopted.

National Health Service (NHS) in England

Since many professionals do not have access to clinical trial bases, in order to facilitate innovation and make it available to all, in January 2016, the NHS announced the creation of seven 'test beds' to partner global innovators with NHS organizations and evaluate the real-world impact of new technologies. These test beds were a successful project that pioneered learning on how to establish data exchange and knowledge governance frameworks, as well as real-world innovation assessments. Their experiences have been documented in instructional manuals so that future Testbeds and the health-care system as a whole might benefit from what they have learned.

India's efforts to protect affordable medical treatments

India decided to put safeguards in place to protect public health and avoid patent misuse, after being forced by the WTO to begin patenting medications in 2005. MSF is continuing to collaborate with civil society to defend India's role as the "pharmacy of the poor world."

Access Campaign of Médecins Sans Frontières (MSF/ Doctors without borders) in 1999

One of the first promising steps towards medical innovation accessibility was the Access Campaign of Médecins Sans Frontières (MSF) in 1999. Patents, intellectual property, and trade restrictions, as well as research and development (R&D) policies, are among the hurdles that the team aimed to overcome. Then, after the MSF received the Nobel Peace Prize in October of the same year, the monies received were used to advance accessibility to treatments and research for neglected diseases.

POSSIBLE SOLUTIONS

International trade

International trade facilitates access to medications, especially for less economically developed countries lacking local manufacturing capacity. Trade increases competition and promotes economies of scale, which lowers costs and expands the number of suppliers available, enhancing supply stability. To various degrees, all countries rely on foreign products to meet their populations' health-care needs. In most countries, particularly in smaller developing economies with little or no local manufacturing capacity in medical technologies, such imported products contribute significantly to the country's national health system. Countries are also becoming

more involved in the trade of health-care services. Thus, trade policy influences how marketplaces for healthcare technology are opened to competitors in the market from imports of goods and services.

The World Trade Organization (WTO) establishes multilateral rules for international trade. Non-discrimination in world trade is one of the WTO's pillars. This is achieved through the implementation of the principles of national treatment and most-favored-nation (MFN) treatment.

Information-based research

Intellectual Property protection works in favor of market-based incentives as well as investing in innovative technology of product development and marketing. Due to the significant financial and technical resources required, as well as the high chances of failure even at the latest stage in product development and difficulties linked to product liability, such incentives are particularly important for the development of medical innovations. Furthermore, there is a requirement for a strict regulatory framework for evaluating medical technologies in terms of quality, safety, and efficacy. Information-based research enhances faster results and less costly practices than experimental studies, by using health information databases. It can process big quantities of information and uncover unanticipated occurrences or differences among population subgroups. Since it does not include an ethical or technical aspect, and is based on the re-evaluation of data, it facilitates the transition to personalized treatment, making health research easily accessible to individuals, and relying on genetic composition and health history.

Open access to test data

Open access to data is a promising solution when it comes to promoting access to medical innovation by creating a new medical research landscape. By open access to test data, where studies would be published in a virtual environment, providing unrestricted and quick online access to professional research, we essentially facilitate innovative activities that aim in developing new medicines, since there is no need for duplication of clinical trials. Thus, researchers are able to examine clinical trial data faster, come up with solutions that may be needed, and make them accessible to the public more quickly, while helping cure medical conditions through collaboration. On the other hand, while the reader is not charged for open access, the expense is borne by the researchers. As a result, if the publishers do not have the finances up front, these charges might preclude them from publishing their work at all. In addition, even though the worries about the quality of open access research keep diminishing, the problem remains. More specifically, according to a 2014 poll

conducted by Nature Publishing Group and Palgrave Macmillan, 41% of academics in the humanities, business, and social sciences were concerned about the quality of open access publications.

Changing medication development costs

Many studies support that we can encourage access to innovation by cutting medication development costs through worldwide regulatory harmonization. Currently, in most countries, federal law prevents the negotiation of prescription pricing with manufacturers. As a result, pharmaceutical corporations may charge whatever the market will bear, leaving the government with no choice but to cover numerous treatments at large expense. Attempts to establish mutual recognition of marketing approvals are divisive, although data exchange and shared standards (for example, for biomarker validation) are achievable. For example, even though hepatitis C treatments are highly effective now, their high costs prohibit them from being widely available, particularly in low- and middle-income countries. MSF and other civil society organizations challenged patents and pressed pharmaceutical corporations to lower pricing; in 2017, MSF was able to negotiate a price of $120 per 12-week therapy, which is a fraction of the $147,000 launch price. The MSF Access Campaign continues to campaign for medical R&D that prioritizes the needs of the people we help and provides benefits in the form of medicines, diagnostics, and vaccinations that are affordable.Nevertheless, more study on the costs of the worldwide patient population will also be required.

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