



THE POWER OF COMMUNITIES AGAINST MONOPOLIES

Actions for access to medicines



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FUNDACIÓN GRUPO EFECTO POSITIVO



ABOUT US

Fundación Grupo Efecto Positivo (FGEP) is a CSO founded in 2006 which seeks to improve PLHIV and Hepatitis C's lives. Our goal is *to eliminate barriers to access to essential medicines and services, promoting human rights*. Our Program on Access to Medicines aims to promote universal access to treatment. We highlight the elimination of barriers of Intellectual Property and we work to promote access to integral, sustainable and quality treatment.

HIV WORLDWIDE

By June 2017, 20.9 million of 36.7 million PLHIV had access to treatment. *This means that 43% of PLHIV, 16.8 million people, do not have access to treatment.*

The HIV/AIDS pandemic is a consequence of the human immunodeficiency virus (HIV) transmission worldwide. During the 1980s, some symptoms were identified as acquired immunodeficiency syndrome (AIDS). Since its origin, the number of infected individuals has increased. Thus, government and civil society have taken action in many countries across the world.

There have been global initiatives to stop the epidemics. In 1996, the UN launched the Joint United Nations Programme on HIV/AIDS (UNAIDS), which aims to coordinate global action for the pandemics control.

HIV WORLDWIDE



In 2016, 36.7 million [30.8 million–42.9 million] people were living with HIV.



1.8 million [1.6 million–2.1 million] people were infected with HIV in 2016.



1 million [830.000–1.2 million] people died from AIDS-related illnesses in 2016.



76.1 million [65.2 million–88.0 million] people were infected with HIV since the epidemics origin.



35 million [28.9 million–41.5 million] people died from AIDS-related illnesses since the epidemics origin¹

In fact, after the G8 summit held in Okinawa in 2000, the Global Fund has been fighting against HIV/AIDS, TB and malaria. The Global Fund seeks to accomplish the millennium goal 6, which aims to combat HIV/AIDS, malaria and other diseases.

In 2016, the high-level meeting by the UN General Assembly Special Session (UNGASS) on HIV/AIDS announced the achievement of the millennium goal related to "halt and reverse the AIDS epidemic,"² as well as the statement to end the epidemics by 2030.

¹ Source: Newsletter roadmap 2016 - Global UNAIDS.

² Document of the High Level Panel Meeting to end AIDS, available at: <http://www.unaids.org/es/resources/documents/2016/2016HighLevelMeeting>

CURRENT SITUATION OF HIV/AIDS IN ARGENTINA

Argentina's health system guarantees universal access and coverage of treatment; *access to medicines is a right that must be guaranteed*. The Law 23.798 "National AIDS Law" was established in 1990 and declares of national interest the fight against the pandemic. Since the creation of the National AIDS Program, the Ministry of Health centralized the purchase of medicines and supplies

needed for treatment and its distribution across the country.

The National AIDS and STD Program is an organization that depends on the Ministry of Health and is in charge of promoting guidelines and coordinating national policies on HIV/AIDS. In the newsletter on HIV, AIDS and STD in Argentina N° 34, you can find information related to HIV/AIDS in 2017.



There are around 122 thousand PLHIV in Argentina. 70% of them, 78 thousand people are aware of their condition but nearly 36600 people don't know that are living with HIV.



Around 5500 people got infected with HIV in Argentina in 2017.



1553 people died caused by the epidemics in 2015.

Though the Law 23.798 was a great step forward to address the epidemics and a model in the region, its biomedical approach in the 80s is no longer enough to respond to the needs of affected communities, who were able to increase their survival rate with high quality treatments. Nowadays, civil society is fighting to reform the law that contemplates not only biomedical aspects, but also social factors around the disease; the bill also includes Viral Hepatitis and STD.

ACCESS

AND ESSENTIAL TREATMENT

The development of medical technologies has increased since the first case that originated the epidemics, from monotherapies to the creation of high quality antiretroviral treatment that not only allows people to survive, but also improves the quality of life of PLHIV.

According to newsletter Nº 34 of the DNS and STD in December 2017, *69.200 people get on treatment in Argentina*. 69% of them, 46518 people, obtain assistance and treatment in the public health system. Only 31% receive care in the regular or prepaid insurance sector.



International Congress on Access to Medicines. Picture: José Luis Schanzenbach



BARRIERS

TO ACCESS

From the perspective of health as a human right, medicines are social goods. However, one of the main barriers to access is their price; high prices reduce access possibilities.

Within the framework of the World Trade Organization (WTO) in 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was negotiated, which made compulsory granting patents on medical technologies. This means that *medicines, treatments and all technologies related to medicines have “owners”, and they have exclusive rights over that invention*.

After TRIPS, countries had to adopt their legislations to these new trade rules. With the aim to meet the international commitments as members of the WTO, Argentina adopted the Patents of Invention Law Nº 24.481. This Law grants 20 years exclusivity to patent owners of medical products to produce and trade medicines.

Granting a patent creates a *monopoly that allows their owners to freely price* their protected products, even if this impinges upon health. Prices, then, are fixed way beyond research, development and manufacturing costs, and they are extortive for health systems. Trade rules in the TRIPS exclude thousands of people from accessing medicines, creating barriers and obstacles to health budgets used to purchase medicines, as this prevents the development and commercialization of affordable generics.

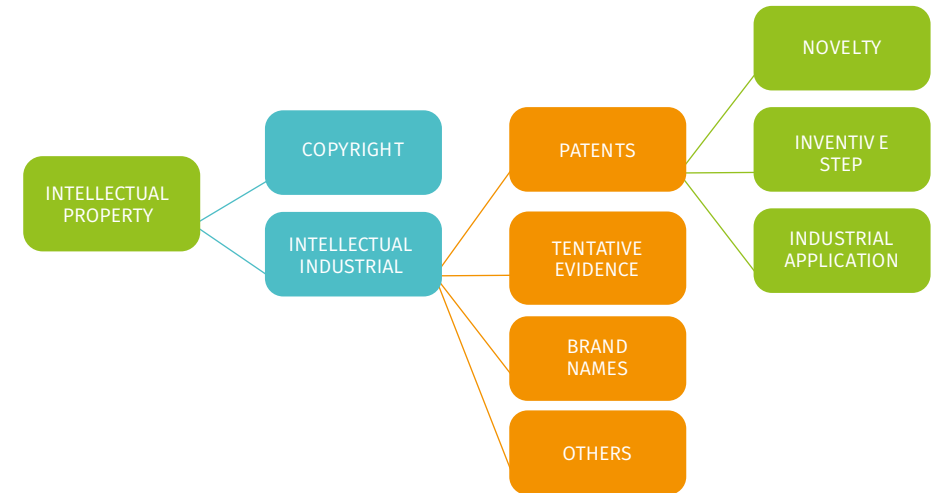
COMMUNITY MOBILIZATION

FOR UNIVERSAL ACCESS TO TREATMENTS

Since the origin of the epidemics and since the creation of high quality medicines, the global movement of civil society for affordable medicines has emerged. Obstacles caused by the high price of medicines made national and international organizations coordinate their efforts to identify causes and act together so affected people, regardless of their nationality, can access treatment in order to improve their life quality.

The reasons why prices of medicines are exorbitantly costly are related to the existence of exclusive rights created by IP.

Since the TRIPS Agreement, developing countries are obliged to grant pharmaceutical patents. This international agreement has given a commercial nature to medical technologies, turning them into commodities, and has caused the spread of patent application worldwide.



In addition, there is a systematic abuse from pharmaceutical companies, which do not hesitate to run over the fundamental rights of the population in

order to fulfill their greed and economic interests. Affected communities have challenged such abuses and actions.

COMPANIES FIGHT

BACK

In 2007, economic interests of pharmaceutical companies were exhibited, once again, in another controversial case. Novartis, a Swiss pharmaceutical company, brought a lawsuit against the Indian state in order to change Section 3(d) of its patent law that establishes health safeguards.

Novartis claimed to patent Imatinib, a medicine to treat cancer. Novartis' unscrupulous strategy caused the mobilization of organizations of affected people and activists on access to health and treatment. Not only did they

FIGHT BACK

C O M P A N I E S

show the impact patents have on access, but also the extortive actions of companies to guarantee their profit.

Years later, the Novartis case against the Indian government was positive. The protection of one of the most important and preventive safeguards was prioritized: the right to determine patentability criteria.

In 2013, Cámara Argentina de Especialidades Medicinales (CAEME), a trade association that represents multinational pharmaceutical companies in Argentina, took legal action against the State. Their goal was to override the guidelines for patentability established through a joint Resolution between INPI, the Ministry of Health and the Ministry of Industry.

Patentability guidelines are an effective tool to control companies' systematic abuse of patents through the strategy of evergreening. These are health safeguards that are under legal attack and are expected to be overridden.

Once more, companies argued that their economic rights had been violated, and the case is still pending. Different sectors of the national industry have joined the case as third parties and have upheld the patentability guidelines, as we have been doing from FGEP, representing the people who need medicines to save their lives.

In Brazil, this is also happening. In 2014, the Pharmaceutical Research Industry Association INTERFARMA, which represents the multinational industry, sued the Brazilian State in order to eliminate patentability criteria used in the mechanism known as "prior consent," which implies a joint evaluation between the patent office and ANVISA for sanitary technologies. This mechanism guarantees the implementation of the health safeguards that are under legal attack. In both cases, the extortive strategy of pharmaceutical companies to favor their interests is very clear.

Due to recommendations of the HIV Commission and the Law, which analyzed the impact Intellectual Property has on access to medical technologies, in December 2016, former UN Secretary-General Ban Ki Moon convened a High-Level Panel on Access to Medicines. The proposed objective was "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international Human Rights law, trade rules and public health in the context of health technologies."

Currently, Executive Director of Fundación Grupo Efecto Positivo (FGEP) and General Coordinator of the Access to Medicines Program (PAM), María Lorena Di Giano, was invited to take part in the Expert Group that advised and supported the High-Level Panel on Access to Medicines and Innovation during 2015 and 2016.

The High-Level Panel prepared a report³ in which Intellectual Property related issues were systematized for the first time, considering more than 180 contributions from different areas: government and organizations, private sector, public and private pharmaceutical industry, CSOs, groups of PLHIV, academics and "Think Tanks," international organizations and independent activists, among others.

This report reflects upon and creates *recommendations about the importance of more transparency when it comes to R&D of medical technologies*. It also focuses on increasing public investment to promote the development of new technologies that meet real healthcare needs of affected people, regardless of their economic status or nationality.

The main recommendation of the High-Level Panel report is that countries should make full use of health safeguards or

³ <https://bit.ly/2fVxnll>

TRIPS flexibilities to guarantee public health needs in relation to Intellectual Property. Moreover, it prioritizes the main safeguard in TRIPS: the countries' right to define patentability criteria to satisfy the requirements of novelty, inventive step and industrial application.

Health safeguards are mechanisms that allow decreasing the impact of patents on access to medicines, since they strengthen countries' sovereignty to interpret and implement the TRIPS Agreement and to protect public health.



Mobilization at the Parliament to further discuss the HIV Bill. Picture: José Luis Schanzenbach

FGEP'S CONTRIBUTION

In FGEP, we use and promote the use of health safeguards included in the TRIPS and in our national Patent Law. Our goal is to *remove Intellectual Property barriers on access to medicines and public health in Argentina.*

We upheld the anti-evergreening patentability guidelines adopted in the Joint Resolution in support of Public Health, and we filed oppositions to patent applications that do not meet the legal requirements. In addition, we did research

and advocacy work in order to use safeguards such as compulsory licenses.

A fundamental basis of our Access to Medicines Program is the development of training activities on access to medicines and IP activities. FGEP carried out capacity building workshops to the Ministry of Health Staff. Also, we work to strengthen and develop skills in activists and organizations, ensuring the promotion of a public debate around access to medical technologies from a human rights perspective.

COLLABORATIVE COMMUNITY WORK AND REGIONAL NETWORKS

We are linked to a network of people in the National Front for PLHIV Health that is composed by 60 networks and organizations of PLHIV in Argentina. We are also linked to Human Rights organizations of affected communities and community organizations.

At regional level, we are co-founders and coordinate the Regional Secretariat of Red Latinoamericana por el Acceso a Medicamentos (RedLAM), which is composed of: ABIA/GTPI, Asociación Brasileña Interdisciplinaria de Sida -Grupo de Trabajo sobre Propiedad Intelectual (GTPI); Acción Internacional para la Salud (AIS) from Peru; Red Mexicana de personas viviendo con VIH/Sida, and Fundación Ifarma from Colombia.

In addition, we coordinate global efforts with the Make Medicines Affordable campaign regulated by the International Treatment Preparedness Coalition (ITPC Global) in the context of the International Organizations Consortium that implements the project "Access to Medicines for People with HIV in Middle Income Countries" and that receives support from UNITAID/WHO. Participants of this campaign are: ABIA (Brazil); Associação Brasileira Interdisciplinar de AIDS (Brazil); AIDS from Thailand; Ukrainian Network of PLHIV and the Initiative for Medicines, Access and Knowledge (I-MAK), based in U.S.

FGEP CONTRIBUTION

We implemented the Access to Medicines Program, with five countries, planning and implementing the following strategies:

- ✓ Promoting the implementation and use of health safeguards included in the TRIPS and the Doha Declaration about TRIPS and Public Health.
- ✓ Promoting and pushing through legislative and regulatory reforms in order to ensure the full achievement of human rights.
- ✓ Strengthening and empowering organizations and leaders on the exercise of fundamental Human Rights.
- ✓ Promoting the availability of generic medicines in the market and in local production, thus facilitating universal access to sustainable and quality treatments.
- ✓ Influencing public debate with decision makers in order to improve access to information, services and integral treatments for affected communities.
- ✓ Participating in decision-making spaces of public health policies at national, regional and global levels.





MYTHS AND TRUTHS AROUND HIV



Why we speak of PLHIV instead of patients living with AIDS? What is an antiretroviral treatment? Is it the same to buy original or generic medicines? Can we produce them in our country? What are we talking about when we say price of medicines and what does the term "cost" mean? Is it the same?

In this publication we intend to address all these questions in depth, answering basic questions, myths and truths around HIV.

ARE PEOPLE **PATIENTS WITH HIV** **PATIENTS WITH AIDS** **O PLHIV?**

To begin with, the affections people may have must not condition their identity. To say that someone is "HIV positive" means that this person is defined by their state of health; there *is nothing as painful and sickening as consolidating the identity of a person.*

Thus, we first talk about people and, in order to do so, we refer to them as such. We also replace the verb "be" with "have." A person is not "HIV positive" but a person living with HIV.

We neither use the term "patient." Etymologically, this word comes from Latin: *patiens* (sufferer), participle of *pati, patior* (suffer). Then, a patient is someone who suffers from an illness and waits passively for medical attention. In this way, we are not considering PLHIV as social beings and rights-holders.

PLHIV integrate an organized community that claims and demands access to medicines and respect for fundamental rights to health and Human Rights. Hence, *organizations and networks of PLHIV have turned into a key actor in the response to HIV at national, regional and international level.*

To live with HIV is not the same as to suffer from AIDS. HIV infection is a chronic affection but it does not mean that a person with HIV has AIDS. A person has AIDS when the HIV weakens the immune system and the clinical picture makes the person vulnerable to develop opportunistic infections or tumors. Antiretroviral treatments prevent a person with HIV from developing AIDS, allowing the development of good living conditions.

WHAT ARE WE TALKING ABOUT WHEN WE SAY **TREATMENTS** HOW DO WE ACCESS THEM?

HIV infection is chronic, and when a person takes the medicines they can stop the impairment of the immune system. High-quality antiretroviral treatment is available since mid '90s.

Since the origins of the epidemics, medical technologies have advanced (from monotherapies to the creation of antiretroviral therapies) and, today, they have not only *allowed survival, but also improved the quality of life of PLHIV.*

Nowadays, the treatment used is the Antiretroviral Therapy of Great Activity, a set of 3 or 4 combinations of antiretroviral drugs that act in different phases of the progression of HIV. Antiretroviral drugs attack the retrovirus by decreasing the virus presence in blood. This allows the immune system to recover its capacity to resist infections.

WHAT POLICIES DOES THE STATE HAVE FOR PLHIV?

Most countries have HIV/AIDS programs which aim to guarantee that PLHIV have access to medicines, services and supplies to treat health. Thus, the State provides populations preventive tools to stop virus transmission. In Argentina, medicines are provided freely to all people receiving attention in the public health system, members of health insurance services and prepaid insurances.

In 1982, the Ministry of Health and Social Action in Argentina included this illness in the Department of STDs, divisional of the National Program of Promotion and Protection of Health. In 1990, it was established the Law N° 23.798 National AIDS Law and the regulatory decree 1244. In 1995, it was established the Law 24.455 of health insurance coverage and in 1997 the Law 24.754, which makes compulsory social assistance to prepaid insurance for attention and integral treatment of PLHIV.

In the Law 23.798, *the struggle against the epidemics was declared of public interest* and in the article 4 it was established that *sanitary authorities should develop programs for HIV/AIDS.* In addition, it was agreed that *the law should apply to all the Argentinian territory* and the authority would be the Ministry of Health. The general goal of the program was to reduce the spreading of HIV and STDs, providing attention to PLHIV and minimizing the biological, psychological and socioeconomic impact of the epidemics. Moreover, this Program had two courses of action: diagnostic and distribution of medicines.

In the following decade, the Program was promoted to National Program. Nowadays, The National AIDS and STDs Program has a wide vade mecum that includes more than 60 medicines, among them antiretroviral drugs. The list of medicines is updated periodically and includes new available technologies.

In 2012, it was created the National Program of Viral Hepatitis, which was incorporated in the frame of the National AIDS and STDs Program, and it manages the promotion of policies, prevention, capacity building and provision of the necessary resources for diagnostics, follow up and treatment of viral hepatitis. Hep C co-infection is one of the main causes of death of PLHIV.

In 2005, the DAAs entry into the Argentinian market allowed many people to access the cure of Hep C. The treatment consists of a daily intake, depending on the clinical condition, and allows people to cure themselves in 12 weeks since it is around 95% effective. In the past, available treatments to treat Hep C were much less effective, around 50%, and they caused side effects and toxicity.

In 2017, the TB Program was also incorporated into the National AIDS and STDs Program with the goal of strengthening the integral response to TB and treating people that have the most common co-infection related to HIV.

The Bill to reform the old AIDS Law had reached the Parliament. Picture: José Luis Schanzenbach.



WHICH IS THE DIFFERENCE BETWEEN

PIONEER MEDICINES AND GENERICS?

Original medicines are called pioneer medicines. These medicines, developed after a series of research from their chemical synthesis to their use in humans, get the approval and health registration for the first time in a country and can be used for diagnostics, prevention or treatment for particular illnesses or affections.

Products that are known as generic medicines are those that have pharmaceutical equivalence with the pioneer products¹. This means that a given generic medicine meets the same standard of quality, safety and efficacy as the pioneer medicine, composed by the same active ingredient, dose and pharmaceutical form.

In Argentina, the agency in charge of evaluating a medicine and authorizing its use and commercialization is the National Management of Medicines, Food and Medical Technologies (ANMAT).

This institution based their analysis on three principles:



Safety: The medicine should have acceptable levels of toxicity. It must not be a threat to the person.



Efficacy: It obtains the expected effects..



Quality: This is measured for its therapeutic effect.

¹ "Medicines: talking about quality," developed by ABIA- Brazil, 2009.

When a medicine is approved by ANMAT, its quality is guaranteed. Hence, pioneer medicines have the same quality as approved generics. It is important to consider *that in our country, doctors must prescribe medicines with the name of the drugs or active ingredients instead of their brand name*. The Law 25.649 ensures "freedom of prescription," low prices and local production of medicines against multinational monopolies.

Furthermore, *a medicine may be under the protection of a patent*. This means that a medicine is under *monopoly* and only its owner can manufacture and commercialize it. This situation produces *an exorbitant increase of prices* of medicines, since it enables the production of generics and competition.

Patents (monopolies) over medicines cause severe obstacles for accessing the right to health.



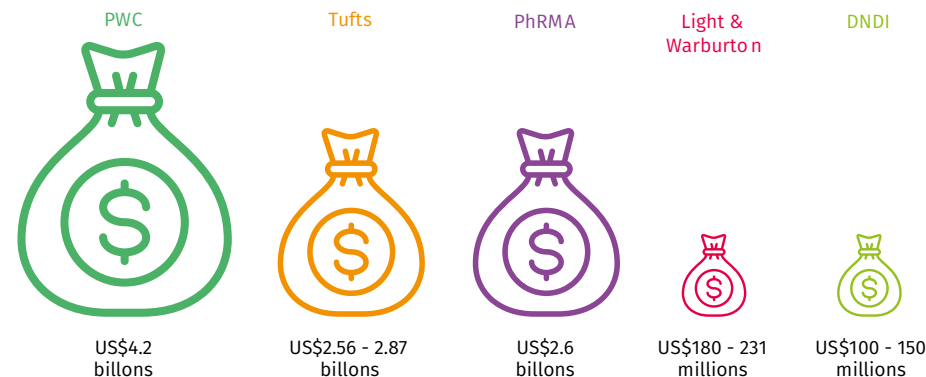
Civil Society mobilized for the new HIV and Viral Hepatitis Law in the symposium of Fundación Huésped. Picture: José Luis Schanzenbach.

IS IT THE SAME TO SAY

PRICE OF MEDICINES OR COSTS?

Historically, pharmaceutical companies have been reluctant to explain which the actual R&D costs to obtain a medicine are. However, there are studies that show there is a *huge difference between prices and development and production costs*.

Estimations about Research and Development (R&D) costs

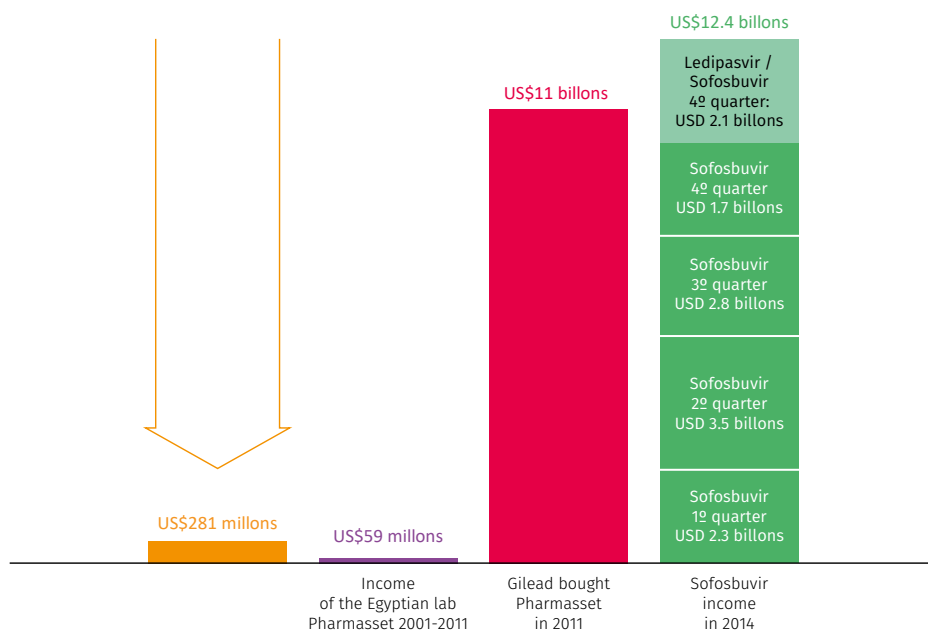


Pharmaceutical companies take advantage of the lack of transparency in R&D, and the exclusivity situation of a medicine in the market may have to impose *extortive prices*.

Nowadays, the business model related to pharmaceutical companies has nothing to do with the traditional view of a laboratory that aims to develop new medicines. Most of the pharmaceutical companies that are in the market do not invest in R&D.

The pharmaceutical company Gilead is known for having purchased from the Egyptian laboratory Pharmasset the technology to produce Sofosbuvir. Due to the patents Gilead claimed, it achieved winnings of billions of dollars during the first year of sales in the U.S.: they put *Sofosbuvir* in the U.S. market to *USD 84.000 per treatment* for 12 weeks, in other words, *1.000 dollars per pill*.

Gilead filed thousands of patents on Sofosbuvir worldwide in order to obtain monopolies over technologies that they did not develop and that are not innovative.



The granting of undeserved patents prevents access to treatment that cures illnesses.

In Argentina, Gilead filed at least 15 patent claims over Sofosbuvir. *FGEP and the organizations involved filed oppositions to patent applications of the company.* We confirmed that its claims do not meet the legal requirements established in the Patent Law 24.481 which indicate that for a medicine to be patented it must be new, it must mean a step forward for science and it should have industrial application.

IS IT THE SAME TO SAY

PRICE OF MEDICAMENTS OR COSTS?

In Argentina, the Patent Office issued on one of the pending files over Sofosbuvir and rejected the patent application over this medicine prodrug. This resolution is very important since it means a step forward for the protection of the production of local generic medicines of Sofosbuvir that compete in the market with a much lower price.

In March 2018, the government bought 1460 treatments to a national supplier, which means savings of *7.5 million dollars or 210 million pesos* in comparison with the price paid to Gilead per treatment in 2016.

In the report of the High-Level Panel on Access to Medicines and Innovation in 2015, convened by former UN Secretary-General Ban Ki Moon, barriers caused by Intellectual Property on Access to Medicines were systematized for the first time.

This report revealed that *the current patent system* (innovation and development) *is in crisis*. This system was adopted through TRIPS, considering that granting exclusive rights over medicines would boost investment on research and development of new healthcare technologies.

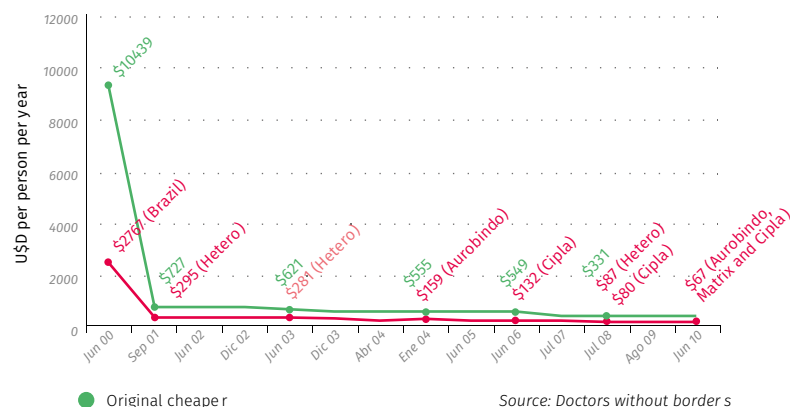
However, in the years this system was implemented, there has been a slight development of new technologies. The pharmaceutical industry multiplied its abusive practices in order to extend their monopolies and winnings through evergreening or re-patenting of already known medicines. *The profit-seeking patent system is a system designed by and for companies.*

NEEDS MARKET

SHOULD HAVE BEEN NEVER DELEGATED TO THE

The University of Liverpool carried out a study² where they analyzed the cost of production and prices of original drugs, with the aim to display the extortive strategy. In the case of Sofosbuvir, the study revealed that the cost of production of the 12-week treatment was US\$ 62, while its price in the U.S. during 2016 was US\$ 49 680³. That year, *in Argentina, the generic version of Sofosbuvir for 12 weeks costed U\$D 1330 and the original U\$D 5541.*

In this chart, we can see how available generics in the market make treatments more affordable:



As we can see, it is extremely important to work on removing barriers to access to medicines. *We, CSOs, use legal tools that allow us to intervene in the abuses of pharmaceutical companies related to the patent system.*

The removal of Intellectual Property barriers, caused by evergreening, allows us to promote development and the entry into the market of generic versions of products. They also favor price competition, an effective method to reduce the prices of medicines.

In 2016, FGEP organized the "International Congress on Access to Medicines and Medical Technologies." One of the most important debates was the system of R+D for healthcare technologies. This congress was attended by more than 100 guests and assistants, including some international representatives on the matter.

² Estimated costs of production and potential prices for the WHO Essential Medicines List. Andrew M Hill Department of Translational Medicine, University of Liverpool, Liverpool, UK; Melissa J Barber-Harvard T.H. Chan School of Public Health, Boston, Massachusetts, U.S.; Dzintars Gotham Faculty of Medicine, Imperial College London, London, UK.

³ Data taken from Melissa Barber's presentation, representing the University of Liverpool at the International Congress on Access to Medicines and Medical Technologies, Buenos Aires, November 2016.

WHICH MEASURES ARE NECESSARY FOR MEDICINES TO BE AFFORDABLE?

As we mentioned before, it is important to use health safeguards to avoid undeserved monopolies and to promote generic medicines. In addition, generic versions can be produced in the country, which would lead to innovation and employment increase.

In the national private sector, there are around 7 laboratories that produce antiretroviral medicines for HIV and DAAs. These laboratories have participated in the bids and public purchases made by the State during the last years. *In all cases where there is price competition, the purchase is done by a local generic producer.*

In 2011, it was established the Law N° 26.688 Promotion of Public Production of Medicines. Three years later, it was created the National Agency of Public Laboratories (ANLAP) with the objective of planning and coordinating the production according to the demand, regulations, accurate use of resources, and inclusion of technologies.

ANLAP would facilitate the management and increase of plants in the medium and long term. Moreover, as part of the Agency strategy, ANLAP articulated with academics through universities and groups of research and regional economies to achieve a potential development of plants.

Though public laboratories have produced and provided medicines to "Plan Remediar" and to some programs of essential medicine provision, there have been no steps forward in producing antiretroviral medicines yet. In 2017, the challenge to produce these high-price medicines was part of the Cooperation Agreement signed by 22 laboratories, ANLAP and the Ministry of Health.

It is extremely important that States prioritize price competition in public purchases. They should also promote the development of the private industry, in particular of those that do not extend the restrictions of the intellectual property regime.

FGEP promotes public production of medicines as a strategy that increases access to treatment and that protects Public Health.





CIVIL SOCIETY AND PUBLIC POLICIES

FGEP's Observatory on Access to Medicines



In Argentina, the health system is composed of three health subsystems:

- ✓ The system of health insurance provides service to employees and it is related to and articulated by the labor union structure.
- ✓ The private subsystem: prepaid and regular health insurance.
- ✓ The public subsystem provides service to everyone through hospitals and clinics.

More than 60% of PLHIV in our country are recipients of the public health subsystem. The Ministry of Health, through the National AIDS and STD Program, is the entity in charge of purchasing medicines and supplies. It also manages logistics and distribution to all provinces and public health services across the country.

According to statistics of the National AIDS and STD Program during 2016, 46518 people received treatment for HIV/AIDS and 1459 received treatment for Hep C.

The term "access" is complex and involves several variables. The price or "affordability" is one of them, and it is relevant to the features of Argentina's health system.

Civil Society role is related to monitoring the implementation of public policies; this should allow mobilization and questioning in order to influence decision makers, and it should also carry the needs of the affected population from a human rights perspective.

*Fundación Grupo Efecto Positivo has developed the **Observatory on Access to Medicines** since 2015 with the goal of observing availability of medicines, public*

investment and participation of the national industry, both in the public and private production, in the purchases of the Ministry of Health.

In the context of access to medicines, observation of the public purchases and its characteristics means a key advocacy tool that allows us to set priorities concerning medicines through advocacy with decision makers and filing oppositions to patent applications that do not meet legal requirements.

This advocacy allows us to contribute to guaranteeing universal access to treatment and influence its affordability to guarantee sustainability. . In Argentina, this has meant savings of 33 million dollars in 2015.

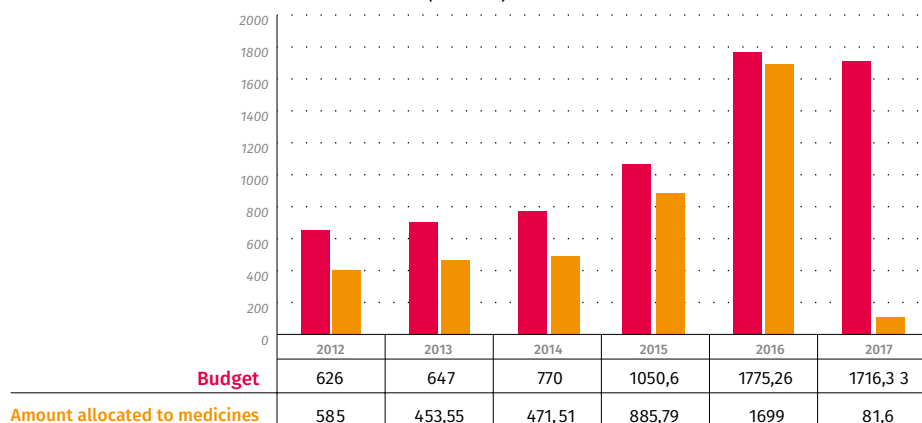
In the Observatory on Access to Medicines, we undertake a follow-up of 38 antiretroviral drugs of them pediatrics and 5 DAAs to treat Hep C. We include 43 medicines considering the national treatment guidelines, their presence in the National AIDS and STDs Program vade mecum and the amount of people under treatment at national level.

MAIN RESULTS

OF THE OBSERVATORY ON ACCESS TO MEDICINES

The budget allocated to the National AIDS Program has increased over the years, as well as the investment on medicines, except in 2017:

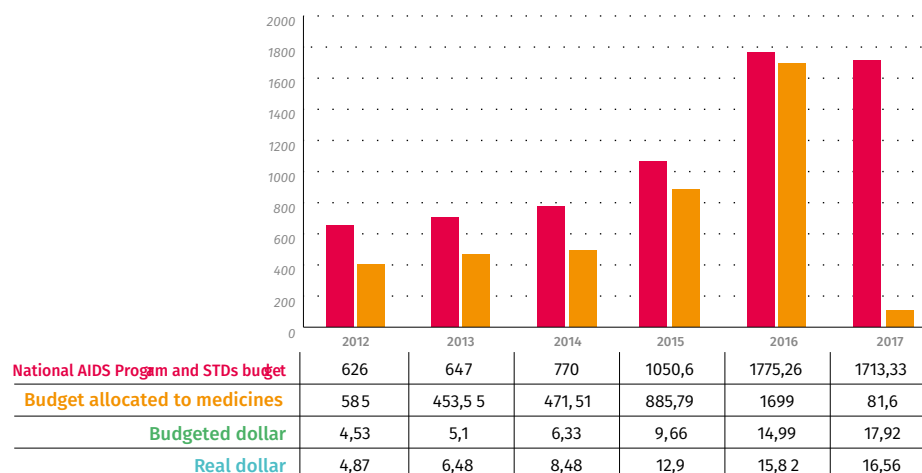
Comparison between the National AIDS Program and STDs and investment on medicines (dollars)



In the graphic, we observe that the investment on medicines takes up a significant percentage of the Program budget, which has even increased in the last years. This information is significant since this entity's responsibilities not only cover the provision of treatment, but also the development and implementation of programs and provision of supplies related to care, diagnostics and prevention. *The more the government invests on medicines, the less are the resources available for other activities.*

In turn, in the last years there have been more technologies available, such as Sofosbuvir, to treat Hep C. When we observe the fluctuations of the dollar rate during the last years, there is a relation between the budget increase and the investment on medicines.

Fluctuations on the National AIDS Program and STDs budget in relation to the budgeted dollar and its real value

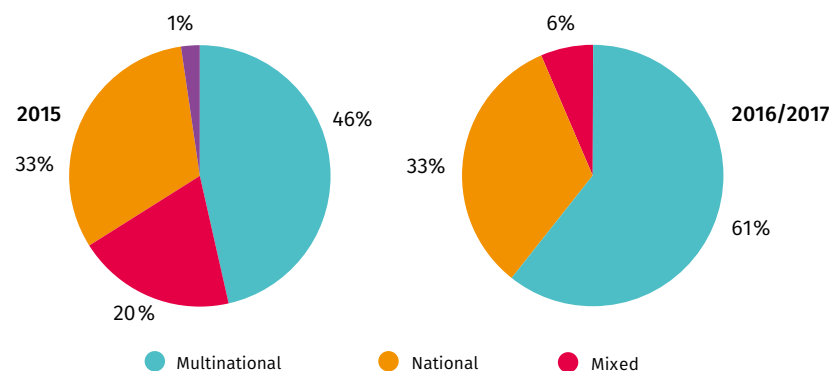


In the graphic, we observe that the dollar rate is relevant in the analysis of the budget and investments intended for medicines. During 2017, the Administrative Coordination of the Ministry of Health did not make the necessary purchases, as illustrated in the previous graphics, which caused the lack of medicines in some public health services. *When there is a lack of medicines and supplies for treatments, the networks of PLHIV and other HIV-related organizations use all the strategies to demand their violated rights.*

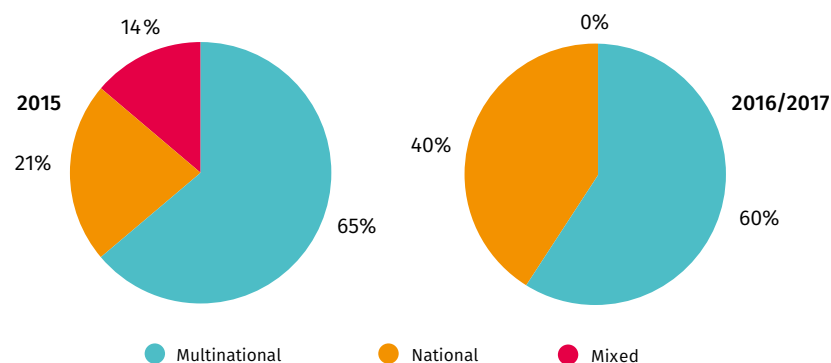
WHO ARE THE MEDICINE SUPPLIERS?

The information we compile in the **Observatory** can be divided into two phases. On the one hand, we take 2015; on the other hand, we take the purchases made in 2016 and 2017. We gather these two years because in 2017 the government only purchased 4 medicines, providing insufficient information to the development of the annual systematization.

When analyzing if purchases have been made from national or multinational companies or both, the result is the following:



If we consider the distribution of investments coming from laboratories, the following distribution can be found:



HOW DOES THE GOVERNMENT PURCHASE MEDICINES?

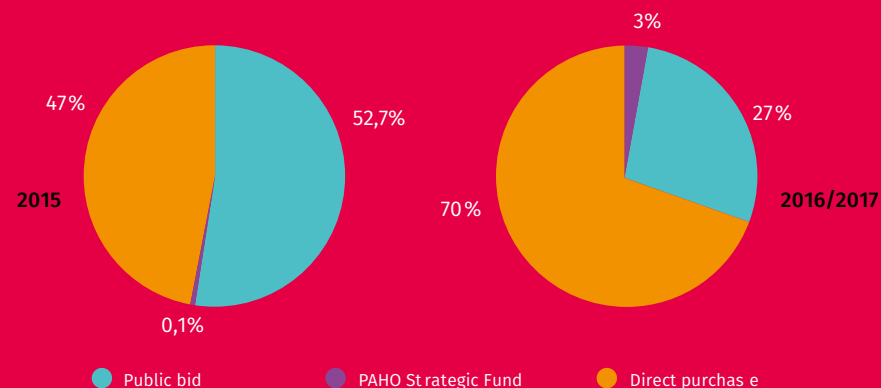
The government can purchase medicines through three mechanisms: public bid, direct purchase (for urgency or exclusivity) and through the Strategic Fund of the Pan American Health Organization (PAHO).

Bidding processes are the most transparent mechanism since they allow price competition. Through this competition, the offers are better and the government can buy treatment for better prices, and this may contribute to sustainability of the provision.

In the case of direct purchase (for urgency or exclusivity), the government's bargain strategies and mechanisms are limited.

The last strategy is the Strategic Fund of the Pan American Health Organization (PAHO), a supportive mechanism of joint purchases between 27 countries of Latin America and the Caribbean. Due to the strengthening of the demands and scale purchases, prices may be more competitive. There is a list of medicines that can be purchased through this fund³.

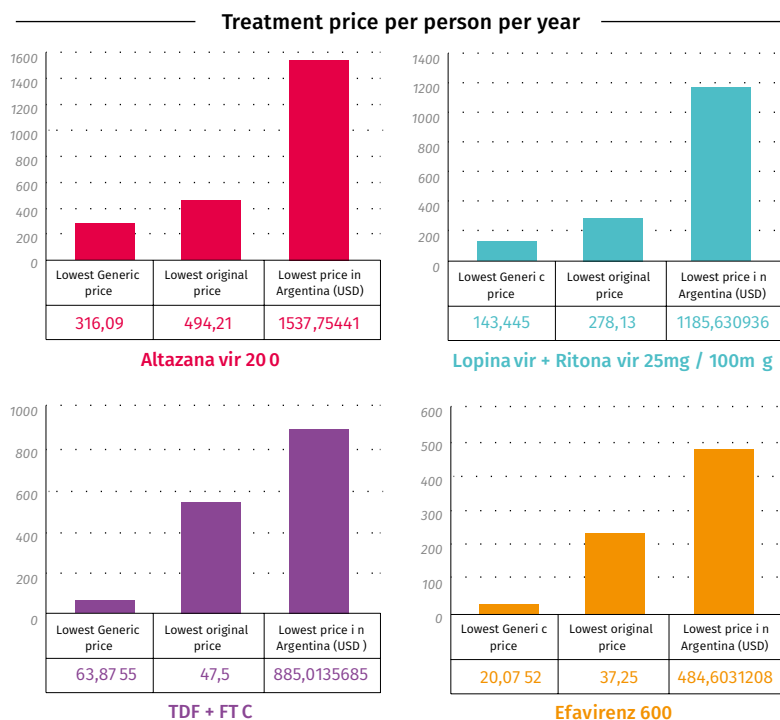
When analyzing the purchase mechanisms of the government between 2015 and 2016/2017, we could observe the different types of purchases:



³ More info at: https://www.paho.org/hq/index.php?option=com_content&view=article&id=12163%3Apan-american-strategic-fund&catid=8775%3Aabout&Itemid=42005&lang=es

WHICH ARE THE PRICES IN ARGENTINA IN COMPARISON WITH OTHER COUNTRIES?

Since we have the systematization of our country's price information, it was necessary to compare medicine prices in other countries of the region and worldwide.

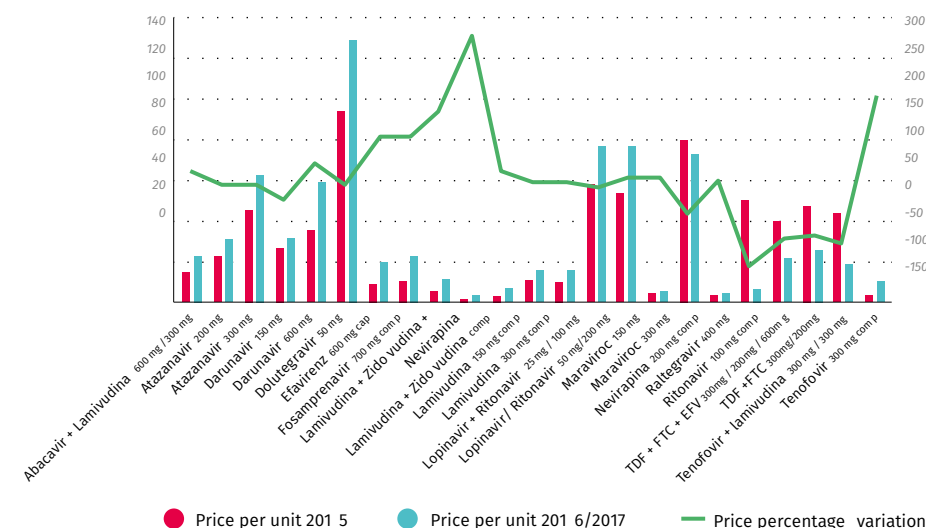


In these graphics with international information from *Untangling the Web* by Doctors without Borders⁴, we observe the price per treatment in dollars per year in Argentina, opposed to the lowest originator price and the cheapest generic worldwide.

⁴ <https://www.msfaaccess.org/common-tags/untangling-web>

THE PRICES OF ALL MEDICINES INCREASE EQUALLY?

Even though the average increase of prices is 48.84% more on each medicine, we observe that price differences between 2015 and 2016/2017 have not been proportional, as shown in the following chart:



In the right column, we observed the percentage price variation between 2015 and 2016/2017. In some cases, there has been a 100% increase. In the case of Lamivudine 150 mg, the increase scales up to 268%. However, we may also see a decrease in the price of 5 analyzed medicines.

These medicines are Tenofovir (TDF); Tenofovir (TDF) + Lamivudine; Tenofovir (TDF) + Emtricitabine (FTC); and Tenofovir (TDF) + Emtricitabine (FTC) + Efavirenz (EFV).

In September 2015, the National AIDS Program made the first purchase of generic antiretroviral drugs through the PAHO Strategic Fund from an Indian laboratory. This mechanism was used in the following years for the purchase of this combination.

In a political context, where health comes before the economic interests of pharmaceutical companies, FGEP could influence public policies, generating savings of US\$ 33.000.000 in 2015 from the purchase of generics for the TDF+FTC+EFV combination and the TDF+FTC combination. In the case of TDF+FTC, and due to the rejection of the patents over this combination in our country, The Ministry of Health could obtain a more affordable local generic.

MAIN CONCLUSIONS

OF THE OBSERVATORY ON PUBLIC PURCHASES 2015-2017

According to the analysis of the public purchases made between 2015 and 2017, we can say:

- ☑ Medicine investment increased exponentially in the National AIDS and STDs Program budget, except in 2017. Last year, the government did not make the necessary purchases to ensure the medicines supply.
- ☑ There is a relation between the estimated budget and the fluctuation of the currency rate.
- ☑ Even though the national industry takes up a significant percentage of the investments, multinational companies are still providing most of the medicines from both perspectives: amount of purchases and amount invested.
- ☑ Purchases made through the bidding mechanism decreased during 2016 and 2017, a variable that impinges upon the increase of prices. On the contrary, we observe more purchases through the PAHO Strategic Fund, a mechanism that allows savings in purchases of medicines.
- ☑ In the international comparative study, by comparing the cheapest generic available with the cheapest original available, the prices paid by Argentina during 2016/2017 were extremely high.
- ☑ Prices increased during 2016 and 2017 an average of 48.84% compared to 2015. These increases have not been distributed equally on medicines, but we observe peaks of 250% of increase in some, and it decreased in 5 of the medicines analyzed. In some cases, opposed to what happened in 2015, medicines were purchased to generic producers.

RECOMMENDATIONS

Public purchases should be done annually for people under treatment; this regularity will allow the improvement of the provision and, consequently, access.

It is necessary to plan public purchases beforehand that allow us to implement more efficient medicines: public bidding and the PAHO Strategic Fund.

National production should be increased in order to favor competition in the market and to encourage the public production of supplies and medicines as social goods.

The government should encourage policies of medicines price regulation that protect the national budget.

It is extremely important to use public health safeguards to avoid monopolies and contribute to the sustainability of treatments.

LIST

OF ANALYSED MEDICINES

Drug	Daily intake	Drug	Daily intake
Abacavir + lamivudina 600mg /300 mg	1	Nevirapina 200 mg com p	2
Abacavir 300 mg cap	2	Raltegravir 100 mg	2
Atazanavir 200mg	2	Raltegravir 400 mg	2
Atazanavir 300mg	1	Ritonavir 100 mg com p	2
Darunavir 150 mg	6	TDF + FTC + EFV 300mg / 200mg / 600m g	1
Darunavir 600mg	2	TDF +FTC 300mg/200mg	1
Darunavir (800) + Ritonavir (100)	1	Tenofovir + lamivudina 300 mg / 300 m g	1
Darunavir (600) + Ritonavir (100)	2	Tenofovir 300 mg com p	1
Dolutegravir 50 mg	1	Zidovudina 100 mg ca p	6
Efavirenz 200 mg cap s	3		
Efavirenz 600 mg ca p	1	Lamivudina 10 mg	-
Etravirina 200 mg	2	Lopinavir/ Ritonavir jarabe	-
Fosamprenavir 700 mg com p	4	Nevirapina jarabe	-
Lamivudina + Zid ovudina + Nevirapina	2	Fosamprenavir 50 mg ja rabe	-
Lamivudina + Zid ovudina comp	2		
Lamivudina 150 mg comp	2	Sofosbuvir	1
Lamivudina 300 mg com p	1	Ribavirina 200 mg Cap	6
Lopinavir + Ritonavir 25 mg / 100 mg	3	Telaprevir 375 mg	6
Lopinavir/ Ritonavir 50mg/200mg	4	Tipranavir 250 mg cap	4
Maraviroc 150 mg	2	Daclatasvir	1
Maraviroc 300 mg	2		





HOW CAN WE AVOID MONOPOLIES AND HIGH PRICES?



With the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO), commercial regulations were applied to medical technologies, at expense of the right to Health.

All WTO member states must adapt their legislation to this agreement, limiting the freedom to define their own policy around intellectual property. The Argentinian Law N° 24.481¹, dictated to comply with the TRIPS agreement, adopted the minimum standard of protection of intellectual property and established three requirements for granting a patent: novelty, inventive step and industrial application. When these patents are granted, they create monopolies with extortive prices.

CS have been mobilizing to reject the high prices imposed by pharmaceutical companies, since they do not allow access, limiting the right to health for those who need it.

From FGEP, along with the organizations of Red Latinoamericana de Acceso a Medicamentos (RedLAM), *we undertook advocacy activities for governments to make full use of their right to use health safeguards.*

The TRIPS agreement establishes that the State can “be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”² In the Doha Declaration it is established that: “the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health. Accordingly, the Doha Declaration enshrines the

¹ Law N° 24.481 of Patents of Invention and Utility Models

² TRIPS Article 1.1

principles WHO has publicly advocated and advanced over the years, *namely the re-affirmation of the members' rights to use fully the safeguard provisions of the TRIPS Agreement in order to protect public health, and enhance access to medicines.*"

In this sense, the National Patent Law keeps the possibility to use flexibilities or health safeguards: legal tools to promote Public Health.

WHAT IS A HEALTH SAFEGUARD?



Patent oppositions: Is the possibility to file an opposition or wake up call to a patent application that does not meet the requirements established in the Law.



Government use: The executive power can dispose the right of a patent in case of sanitary emergency or national security.



Compulsory licences: It is the temporal suspension of the exclusive rights of the patent owner. It allows the production, use, selling or importation of the patented product or process with no consent needed and paying the owner for the use of the patent.

Also, the owner is recognized the opportunity to adopt and implement complementary policies that establish specific criteria for the patent application examination. That is a faculty recognized in the TRIPS text (art. 8).

PATENTABILITY GUIDELINES

In 2012, the Ministry of Industry, the Institute of Industrial Property (INPI) and the Ministry of Health signed a Joint Resolution³ where the patentability guidelines were established to examine the patent applications over medical technologies.

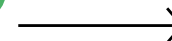
These guidelines did not add new requirements into the Law, but they established stringent criteria to analyze the inventive step, novelty and industrial application. In addition, these guidelines contributed to the examiners work *and promoted the protection of Public Health against the abuses of pharmaceutical companies.*

WHAT PROBLEMS DO THESE GUIDELINES SOLVE?

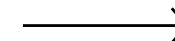
Patentability guidelines solve the practice of evergreening, which postpone the entry of generics into the market.



Original patent
20 years



New Dosage
Extends



New formulation
Extends

³ Joint Resolution between the Ministry of Industry 118/2012, the Ministry of Health 546/2012 and the National Institute of Industrial Property 107/2012.

To avoid this situation, the patentability guidelines allow establishing, in chemical terms, structures that do not meet the requirements of novelty:



By molecular structure:

- ~ Polymorphs
- ~ Pseudo polymorphs (hydrates y solvates)
- ~ Enantiomers



Not patentable due to generic structure are:

- ~ Formulation "Markush" structure
- ~ "Selection patent" application



Not patentable due to chemically-related elements:

- ~ Salts, esters and other derivatives of already known substances
- ~ Active metabolites
- ~ Prodrugs



Not patentable due to its pharmacotechnology:

- ~ Formulations and structures
- ~ Combinations
- ~ Dosing/Doses
- ~ The second medical indication (new medical uses)
- ~ Analogous procedures

Drug combinations are not patentable: according to the law, they are not an innovation. The active ingredients that compose the combinations were already tested in medical practice.

Patentability guidelines are a big step forward for the protection of Public Health and contribute to the accurate management of the patent system that avoids abuses. *However, pharmaceutical companies not only expressed their rejection to the implementation of patentability guidelines, but they also initiated a legal attack intending its annulment.*

COMMUNITARY MOBILIZATION

AGAINST THE JUDICIAL ATTACK ON THE GUIDELINES

In 2013, Cámara Argentina de Especialidades Medicinales (CAEME), which represents multinational pharmaceutical companies, took legal action against the Argentinian State. CAEME claimed "the absolute nullity of the Joint Resolution" and overrule of the guidelines in chemical-pharmaceutical patent applications.

Pharmaceutical companies argued that the guidelines are unconstitutional ; and were dictated by an incompetent entity with no legislative power. Companies also insisted that the Joint Resolution altered the National Patent Law since, according to them, it rewrote –with retroactive effect– the concepts of invention, novelty and inventive step.

In 2015, FGEP presented as a third party in the case file to judicially participate in defense of the guidelines.

The Industrial Chamber of Argentinian Pharmaceutical Laboratories (CILFA), which gathers national generic producers, also intervened as a third party.

Aiming to contribute a technical analysis to be considered by the judge, Centro de Estudios Sociales y Legales (CELS) made a presentation as amicus curiae (advisor to the court). CELS's presentation summed up the contradictions of intellectual property on access to medicines, analyzed the legal aspects of the patentability guidelines, and claimed the rejection of the demand.

In March 2016, the Argentinian State answered the demand by keeping the criteria and arguments that gave rise to the adoption of the guidelines: it was not unconstitutional.

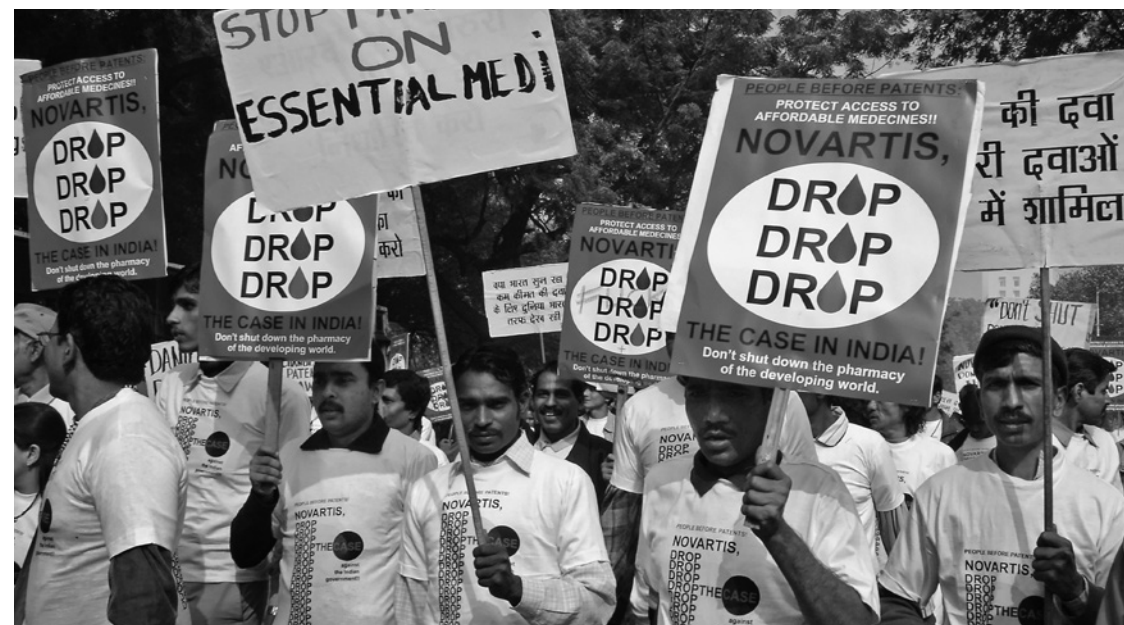
UNITED & ORGANIZED

WE ARE STOPPING THE ADVANCE OF THE
INTERNATIONAL PHARMACEUTICAL INDUSTRY

Pharmaceutical companies' attack on patentability guidelines expressed their abuses in pursuit of economic interests at expense of the human right to Health.

Through the guidelines, *the Argentinian State is acting under the law and exercises its sovereignty*; which is recognized in the TRIPS, in the Doha Declaration and in our Patent Law.

In Brazil, there is a similar situation. Interfarma is the chamber that represents the companies' interests in that country. In 2014, this chamber filed a lawsuit to eliminate the patentability requirements used in the mechanism known as Prior Consent, which implies a joint evaluation between the patent office and ANVISA in the case of patent applications of healthcare technologies.



Multinational companies seek to destroy these mechanisms that limit their abuses. *Interfarma and CAEME are entities that represent their interests in Brazil and Argentina and that have filed court cases that threaten the future of access to medicines in these countries.*

Hence, SC launched a joint campaign to identify and expose these facts. We also wish to call on the national and international community, demanding the pharmaceutical companies to desist or withdraw the cases they initiated.

The campaign is called "Drop the Case" and was presented internationally in 2016 as part of the 31st Session of the UN Human Rights Council.

The litigation continues. We must still make efforts to win the court case in favor of Public Health.

Indian activists in support of the Patent Law in New Delhi, 2017
Picture: Sheila Shettle, Doctors without Borders.

Big Pharma
**DROP
THE CASE**

POLITICAL DECISIONS

THAT ATTACK
THE PATENTABILITY GUIDELINES

Due to the political guidelines adopted by the current Argentinian government, there is a new position in regards to the management of intellectual property.

The National Institute of Industrial Property (INPI) adopted the Resolution N°56/2016 which establishes that *the national office can grant patents in the country without thorough review of the applications, most of which do not meet the legal requirements*. With this new rule, the studies done by the patent office of other countries will be considered to grant patents in Argentina.

In this sense, INPI signed bilateral agreements with developed countries such as the U.S. and Japan. One of the agreements is the Pilot Program (PPH), signed by the United States Patent and Trademark Office and the INPI from Argentina.

The PPH agreement was subscribed as a "Pilot Program"

to avoid its approval at the national Parliament. This way, the president of INPI *avoided a fundamental step compulsory for any agreement that modifies the implementation of the National Law*. The "Pilot Program" also establishes the possibility that the U.S. patent office can be in charge of building capacity of the INPI staff for examiners to continue granting brands and patents according to the criteria established in the U.S.

The standards in both countries are very different. The U.S. has a much more flexible patentability system, which could result in the granting of most of the patents that do not meet the current requirements in Argentina.

After implementing the PPH agreement, examinations made by the patent office in other countries can be used in Argentina. We no longer make our own examinations and they do not meet the requirements established in the law. This means *a loss of sovereignty*.

These policies developed by the president of INPI are a clear step forward against the patentability guidelines that protect Public Health. The granting of patents that do not meet the patentability requirements causes undeserved monopolies that affect the availability and access to essential medicines in favor of economic interests of multinational companies

COMPULSORY LICENCES

Compulsory Licences are a type of safeguard or flexibility originated in the TRIPS that allows countries to limit the exclusive rights of the owners in order to protect Public Health or other general interest. Compulsory licenses are granted to achieve several goals of public policy: to respond to emergencies and needs of public health, to counter anticompetitive commercial practices or to do research. In addition, they are important when there are no substitutes for the products.

We may define them like this:

*"A compulsory license is an **authorization** that a national authority grants to a natural or legal person to make use of the patented product and, to do so, the owner's consent is not necessary. This way, in particular situations, the public interest prevails over the owner's interests."*

Thus, since the origins of the intellectual property system, compulsory licenses are considered an **instrument of public policy** and a way to protect innovations according to people's needs. When we talk about pharmaceutical companies, the public interest is always first: this is implicit and it is not a requirement to proceed.

Compulsory licenses are used to **promote the entry into the market of more affordable generic medicines**. **Compulsory licenses allow the population to access to medicines that otherwise would be impossible to buy**, since its price depends on a monopolistic company.

An example is the license over Efavirenz in Brazil. In this case, the government reduced the price of the medicine more than a 60% compared to the price of the original version of the patent owned by the pharmaceutical company.

Argentina embodied in its legislation the demands of the TRIPS and included, in the same terms of the agreement, the implementation of compulsory licenses under the title "other uses with no authorization of the patent owner."

The Argentinian legislation allows granting compulsory licenses when:

- ☑ **There is a denial to grant a license "in reasonable commercial terms and conditions"** : When a potential user intends to obtain the granting of a license of the patent owner in reasonable terms and conditions, according to the Art. 43, and those attempts are not effective.
- ☑ **There is lack of croft**: The prevision of licenses due to lack of use has been generally based on the traditional role of patents, which are considered a mechanism to favor industrialization and transfer of technologies, based on the "obligation to croft."
- ☑ **There are anticompetitive practices**: This may happen when the behavior is related to the patented product and affects the final consumer or public interest (for example, excessive prices); when this harms competitors or potential patent owners, including the refusal to grant licenses or obstacles to research, and when they are linked to restrictive clauses in agreements of voluntary licenses, for example, in the retrocession of improvements.
- ☑ **Due to healthcare emergency or national security**: Article 45 of Law 24.481 affirms that the executive power is able to, for healthcare emergency, croft certain patents by granting the right of use given by a patent. In regards to health, we consider that patents over products are highly different than other fields since, from the social impact point of view, the protected object is a social good and affects life and health directly.
- ☑ **In the case of dependent patents**: When the croft of a patent depends on another one.

🕒 **Licenses for non-commercial public use:** The government uses the patented object out of the usual trade framework. The "non-commercial sense" is clear in the nature of the transaction (nonprofit) or the purpose (provision the public institutions that do not work as a business).

In the case of research, compulsory licenses may be necessary when patents limit the freedom to operate in the field of Research and Development. In some jurisdictions, exceptions allow to use a patent for experimental uses.

The Article 36 of the Law 24.481 establishes: *"the right conferred by a patent shall have no effect against: a) a third party who privately or in an academic environment and without gainful intent, conducts scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or applies a process identical to the one patented"*.

In Argentina, it was never necessary to issue a compulsory license. However, it is very important to have this tool within our national legislation in the case that people need guarantees for Public Health reasons.

FGEP carried out a study about the national legislation in order to give an advocacy tool in terms of compulsory licenses.



We filed patent oppositions. Picture: José Luis Schanzenbach.



PATENT OPPOSITION: PUBLIC HEALTH SAFEGUARDS



FILLING PATENT OPPOSITIONS:

PUBLIC HEALTH SAFEGUARDS

In 1994, it was adopted the Agreement on Trade-Related Intellectual Aspects of Intellectual Property Rights (TRIPS), which imposed on all WTO member states the obligation to grant intellectual property rights over medicines.

Since the TRIPS agreement, countries had to adopt their legislations to these new commercial rules. To meet the international commitments as a WTO member state, Argentina adopted the Patents of Invention Law N° 24.481. This law grants patent owners exclusive rights over medical products for 20 years to produce and sell medicines.

Countries must have offices in charge of receiving and examining patent applications and determining if they should be granted or rejected based on the requirements established in the law.

Hence, a key health safeguard for civil society is the possibility to *intervene and collaborate in the process of examination of a patent application*. In the article 28 of the Patent Law, any legal or natural person is allowed to file arguments with evidence to the Patent Office in regards to patent applications, aiming to show that it does not meet the patentability requirements.

Oppositions help the examiner, since it not only gives them specific elements to bear in mind, but also "warns" about its importance in terms of Public Health¹.

In addition to defending and demanding the compliance of the guidelines, FGEP has filed oppositions to patent applications that do not meet the legal requirements of novelty, inventive step and industrial application.

OPPOSITIONS FILLED

BY FGEP

Since 2013, we filed six oppositions related to antiretroviral patent applications to treat HIV and DAAs to treat Hep C.. Our work implies the analysis of patent applications over medicines with high relevance in Health, the development of chemical pharmaceutical arguments and provision of evidence to expose the lack of compliance of the patentability requirements.

The filing of oppositions is an essential part of our Program on Access to Medicines and we do it in conjunction with other organizations which joined the global campaign Make Medicines Affordable.



To make the annual comparison easier, we will calculate the prices in dollars.

¹ The Argentinian law establishes that if the filing of oppositions is done within the sixty days of the application, it is called "opposition." If, on the contrary, the patent application is filed after the deadline, it is called a "wake up call." When it is an opposition, the examiner is obliged to take it into account, but when it is a wake up call they do not. As there is no centralized information where applications can be consulted according to the active ingredient to be patented, most of the filing are wake up calls and examiners take them into account in a non-bidding way.



In December 2013, we filed this opposition in conjunction with Red Argentina de Personas Positivas (Redar Argentina). Moreover, we claimed that INPI should prioritize this opposition, since the TDF+EFV+FTC is one of the most used combinations. According to what the Ministry of Health reported, 14384 people were under treatment with this combination.

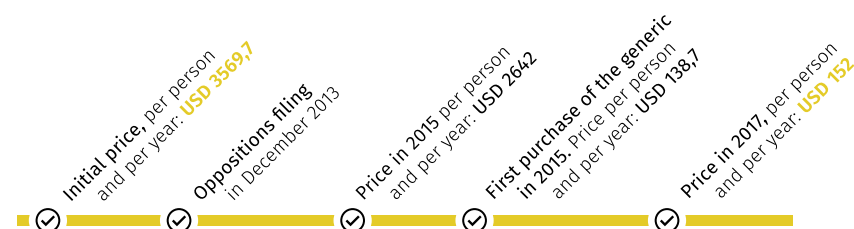
In this moment, we held meetings with healthcare authorities to analyze the opportunity to buy generic versions of the TDF+EFV+FTC combination at more affordable prices. We shared the arguments we filed together at INPI with the Ministry of Health to facilitate the analysis of this situation.

The Ministry of Health purchased the TDF+EFV+FTC combination under the commercial name ATRIPLA® from Gilead, a multinational company that intended a patent over that combination.

Our actions influenced the purchases from 2015: in September, the National AIDS Program of the Ministry of Health made the first purchase of a generic of the TDF+EFV+FTC combination through the PAHO Strategic Fund from an Indian laboratory.

When buying a generic, only in 2015 and through the PAHO Strategic Fund, Argentina could save 20 million dollars. This mechanism was still being used to purchase the combination in the following years. Hence, we can estimate *that between 2015 and 2017 we saved around 118 million dollars.*

Though the application still has not been solved, the impact of filing the opposition and the entry into the market of generic medicines is noticeable.

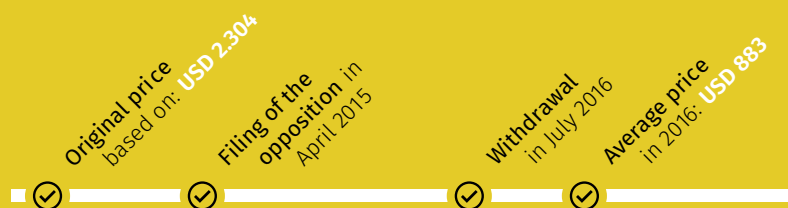




Gilead also intended to obtain the patent over the TDF+FTC combination that is commercialized in Argentina under the brand name Truvada®. In April 2015, we filed the opposition.

A year later, in July 2016, INPI solved the application as a forced withdrawal: Gilead could not answer a series of observations of the examiner, since it was evident that its patent request did not meet the patentability requirements of the Argentinian law.

Impact of the opposition and the withdrawal:



According to the amount of people under treatment with this combination, we calculate savings of 28 million dollars between 2016 and 2017. The possibility to acquire or manufacture generic versions of Truvada would have a significant impact on policies related to HIV/AIDS such as "PrEP" (Pre-Exposure Prophylaxis), recommended by the WHO² and Unicef³ in their treatment guidelines of HIV/AIDS.

PrEP proposes that people who have not had contact with the virus take Truvada to reduce the risk of getting infected with HIV. This policy is highly driven by the United Nations and it part of the current policy promoted as a response to HIV worldwide. If this policy is implemented in Argentina, availability of medicines and sustainability of the public budget may improve due to the acquisition of affordable generic versions. For this reason, it is essential the absence of patents over the necessary drugs for the PrEP.



In 2014, Gilead, undertaking evergreening, intended to obtain a monopoly over a variant of Tenofovir through a patent application at Argentina's INPI.

The company submitted a patent application of TAF (Tenofovir Alafenamide Fumarate), arguing that it was a "new salt," innovative and inventive. However, it was a mere change in a molecule already known and with no patent protection: actually, TAF is a variant of Tenofovir, which is under public domain in our country.

The patent application over TAF did not meet the requirements proposed by the Patent Law and complementary policies. Hence, in February 2018 we filed an opposition for the patent applications to be rejected, arguing and contributing to the evidence of lack of novelty and inventive step. *INPI confirmed our arguments and, from the opposition filed, the patent over the combination was abandoned.*

Gilead had already obtained the registration of ANMAT to commercialize TAF in combination with other drugs such as Descovy, which combines TAF with Emtricitabine, and Genvoya, which combines TAF with Elvitegravir, Cobicistat and Emtricitabine.

If INPI granted, on top of that, the patent over TAF, Gilead would have owned a monopoly over this medicine and other combinations. Then, Gilead could have fixed abusive prices in the market because it would not allow the possibility of having competitive generics in the market.

Gilead has attended national and international congresses and

² Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV: <https://bit.ly/2yTPS6F>

³ UNICEF follow-up to recommendations and decisions of the Joint United Nations Programme on HIV/AIDS 37th and 38th Programme Coordination Board meetings: <https://uni.cf/2yUvann>

conferences with a commercial strategy: trying to replace the medical prescription of TDF with TAF, arguing that the latter provides more clinical advantages and trying to get it in the market.

However, a recent publication of I-MAK⁴ indicated that: "TAF is less likely to cause toxicity in the bones and kidneys, since it has lower doses. Recent Meta-Analysis⁵ shows that there are no significant differences in safety and efficacy between TAF and TDF. At the moment, there is no evidence that TAF is truly more effective than TDF."



Treatment for Hep C is changing quickly. Sofosbuvir and Daclatasvir are part, among other combinations, of the most recommended treatments in the WHO guidelines.

DAA's such as Sofosbuvir and Daclatasvir are much more efficient and safe since they provide 95% of cure rate. They are better tolerated than old treatments, which had much more toxicity and 50% of cure rate.

According to the WHO, although the cost of production is low, DAA's still are very costly in countries of high and middle income. Hence, its price is one of the barriers to access to medicines.

In Argentina, the pharmaceutical company Gilead submitted at least 14 patent applications over Sofosbuvir.

Not all applications include the claims over the product, nor prevent the product from being commercialized in its generic version in our country.

After an exhaustive analysis of the patent applications over Sofosbuvir, FGEP and other organizations we work with considered that the applications do not meet the legal requirements of novelty or inventive step. Thus, we filed two oppositions to the most important patent applications.

Oppositions were filed in two phases. The first one was in May 2015, when we filed the first opposition to the patent application over the Sofosbuvir prodrug. The second one was in February 2017, when we filed the second opposition against the patent application over the base compound of Sofosbuvir.

⁴ "The Roadmap: Special Edition Report on tenofovir alafenamide fumarate. April 2018"

⁵ Hill A, Hughes SL, Gotham D, Pozniak AL. Tenofovir alafenamide versus tenofovir disoproxil fumarate: is there a true difference in efficacy and safety?. J Virus Eradication [Online]. 2018 [cited 2018 Apr 4]; 4: 73–80. Disponible en: <https://bit.ly/2Kzs49v>

The importance of our work on Sofosbuvir is based on the arguments and evidence we developed in FGEP, in conjunction with other organizations. Apart from oppositions, we held a series of key meetings with national producers. They expressed their interest in producing Sofosbuvir, filed patent oppositions and searched for health registration or authorization from ANMAT to commercialize the products.

Currently, there are several health registrations for Sofosbuvir that compete in the market and that allow the Ministry of Health, as happened in the last public purchases of this product, to get significantly lower prices than the prices offered by Gilead, which claims the patent in our country.

Mobilization to the Parliament for the new AIDS bill to be treated . Picture: Jose Luis Schanzenbach.



Medicine	Producer	ANMAT Registration Number
Sofosbuvir 400 mg	Richmond SACIF	57811
Sofosbuvir 400 mg	GADOR SA	57812
Sofosbuvir 400 mg	ULTRA PHARMA SA	57952
Sofosbuvir 400 mg	ELEA SACIFYA	58203
Sofosbuvir 400 mg + ledipasvir 90 mg	GADOR SA	58113



In this case, we can see the impact of public purchase from two Sofosbuvir suppliers, guaranteeing price competition:

<i>Sofosbuvir 400 mg</i>	<i>Price per unit or per pill</i>	<i>Price per treatment per person for 12 week</i>
GILEAD (American company)	AR\$ 975	AR\$ 81.900 (US\$ 5.541,28) March 2016
LABORATORIOS RICHMOND (Argentinian producer)	AR\$ 234	AR\$ 19.656 (US\$ 1.330) March 2016
LABORATORIOS RICHMOND (Argentinian producer)	AR\$ 133	AR\$ 11.172 (US\$ 638) August 2017
ELEA S.A. (Argentinian producer)	AR\$ 86.39	AR\$ 7.257,6 (US\$ 358,62) March 2018

Due to the high prices of Sofosbuvir since its entry into the U.S. market (US\$ 84.000), free medicine provision programs around the world had to resort on the strict definition of access policies. Thus, they prioritized people with severe liver impairment or cirrhosis.

In Argentina, the first purchase was intended for 1200 people who had stages 3 and 4 of Hep C.

The public purchase was made in March 2016 and a local producer, as indicated in chart 1, offered a much lower price than the pharmaceutical company that claims the monopoly (patent). During the following years, local producers were able to reduce even more the price of Sofosbuvir, producing savings for the Argentinian State.

In December 2017, INPI rejected the patent application over the Sofosbuvir prodrug.

The rejection had a great impact on the Argentinian market and meant an important step forward in guaranteeing that local producers remain in the market. This also ensures the commercialization of affordable generic versions through public purchases.

This impact was reflected on the public budget as well. In March 2018, 1460 treatments were bought from a national generic supplier, and this *produced savings of 7.5 million dollars or 210 million pesos* compared with the price paid to Gilead per treatment in 2016.

The impact of the rejection of the patent over the Sofosbuvir prodrug not only was significant for our country, but also for the rest of the world. In many countries, many cases of patents over Sofosbuvir are still pending and, after the resolution in Argentina, the same arguments could be used to analyze similar applications.

OPPOSITION AGAINST THE PATENT APPLICATION OVER **KALETRA®** LOPINAVIR + RITONAVIR

In November 2015, we filed an opposition against the patent application of the American Abbott Laboratories over the Lopinavir+Ritonavir combination.

Abbott had filed countless patent applications over individual drugs and combinations. Abbott already has a patent over the Lopinavir+Ritonavir combination that was used for the first opposition against Kaletra in capsules, when cool chain was necessary. The patent application we opposed to was the alternative to the combination of drugs for manufacturing heat-stable pills.

The goal of this opposition was to avoid extending the protection of the patent for 8 more years. Abbott is a clear example of evergreening implemented by companies to extend their monopolies illegally through successive patent applications over combinations of drugs already known and patented.

From June 2016 to February 2017, the Patent Office in Argentina rejected the patent application of the company AbbVie over the Lopinavir+Ritonavir combination.



In 2016, the Ministry of Health purchased Lopinavir + Ritonavir and obtained savings of 125.000 dollars in relation to the previous purchase.

From FGEP, we have made efforts to guarantee access to medicines, avoiding barriers and influencing public policies in favor of communities with HIV.





FTA'S IMPACT ON ACCESS TO MEDICINES AND THE RIGHT TO HEALTH



In 1994, within the World Trade Organization, it was adopted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which made compulsory the granting of patents over products and processes in terms of health technologies.

WHAT IS A PATENT?

Patents are exclusive rights granted by States over innovative medical technologies. *Patent owners get a 20 year monopoly to produce and commercialize its products and processes.* Patents create monopolies that allow companies to commercialize medicines at extremely high prices, even higher than costs of research, development and manufacturing. Hence, since the adoption of the TRIPS Agreement, medicines started to be considered commercial products, in other words, commodities.

In terms of health, these commercial rules *exclude thousands of people worldwide from access to medicines. They cause a significant increase in the public expenditure and prevents the entry into the market of more affordable generic drugs.*

In countries like Argentina, the increase of prices jeopardizes *sustainability* of the medicines and supplies provision programs in our health system, integrated by the public health system, regular and prepaid insurance.

This situation has exacerbated *since pharmaceutical companies, which seek to secure and extend their monopolies, are putting pressure on the States*. The TRIPS-Plus norms seek to impose measures that widen the protection of Intellectual Property Rights, increasing the TRIPS' minimum protection standards.

There are several strategies used by pharmaceutical companies to impose TRIPS-Plus measures. They generally do so through legislative and regulatory reforms or through the inclusion of "Intellectual Property Chapters" and "Investment Chapters" in the FTA negotiations.



WHICH ARE THE TRIP~PLUS MEASURES?

DATA EXCLUSIVITY

They impede the use of clinical trials data to register generic versions of medicines

INCREASE

of the scope of patents:

The creation of exclusive rights by granting of patents on new forms, new uses or methods of an already known product, as well as patents over diagnostics, therapeutic and surgical methods and biological products.

PATENT TERM EXTENSION

The extensions of a patent's term may be beyond 20 years (TRIPS), for instance, the grant of a compensation for delays in administrative procedures to obtain health registration.

PATENT LINKAGE

}Linkage between patent processes and health registration. It impedes the registration of generic versions of already patented medicines, undermining the TRIPS exceptions, like the Bolar Exception, and exceptions for research.

RESTRICTIONS ON COMPULSORY

licences: They attempt to limit the right of countries to use compulsory licenses to guarantee universal access to medicines.

RESTRICTIONS IN THE USE

of patent oppositions: Elimination of the possibility to use patent oppositions mechanisms to promote Access to Medicines.

BORDER MEASURES

The execution of border rights to seize and destroy generic products in transit, without intervention of the buyer, alleging they are "falsified products."

RESTRICTIONS ON PARALLEL

licences: They impede patented medicines to be imported from any country at lower prices.

RULES ON INVESTMENT

They allow foreign companies to sue governments through private arbitration, challenging national Health policies such as measures for price reduction. They can prevent governments from promoting local production.

INJUNCTIONS

(Restriction of the use of judicial preventive measures): They undermine the judicial power independence in developing countries to protect the Right to Health.



DO WE HAVE TRIP-PLUS MEASURES IN ARGENTINA?

From Red Latinoamericana por el Acceso a Medicamentos -RedLAM-, a network coordinated by FGEP, we undertook a study on intellectual property legislations and regulations in four Latin American countries (Argentina, Brazil, Colombia and Peru).

This study showed that Argentina is the only country that has not widened intellectual property and has not incorporated TRIPS-Plus measures. In addition, it adopted measures and strict patent examination criteria to protect public health. These measures can be found in the Joint Resolution 118/2012, 546/2012 and 107/2012 signed by INPI (Instituto Nacional de Propiedad Industrial), the Ministry of Industry and the Ministry of Health.

However, multinational pharmaceutical companies have tried to use the judicial power to challenge these advances. Novartis has tried to restrict the entry into the market of generic medicines through legal action, aiming to obtain the protection of data exclusivity that has been rejected in Argentina in 2011. In 2013, Argentina's CAEME (Argentine Chamber of Multinational Pharmaceutical companies) sued the national government and requested the nullity of the Joint Resolution that establishes patentability guidelines. *If CAEME's demand is successful, access to health will be jeopardized. Thus, FGEP filed a request of contribute as a third interested party in the trial and contributed to the defense of the guidelines. CAEME opposed to FGEP presentation. After litigation the Judge deemed FGEP legitimacy to intervene in the judicial case.*

The Free Trade Agreement represents a *genuine threat* in terms of TRIPS-Plus measures for the right to health.



WHAT IS A FTA?

A FTA (Free Trade Agreement) is a commercial negotiation between two or more countries where they grant tariff preferences to exchange goods and services. In general, these agreements are negotiated behind the backs of people and representatives and modify laws to protect commercial rights of actual recipients.

In the last years, multilateral entities have been left out so the most powerful countries can impose their economic guidelines. Thus, signing of FTAs has spread.

Latin America was a suitable place to include the FTA with TRIPS-Plus measures. En some cases, these agreements were accepted without negotiating an adjustment to the "development" conditions of each country. For example: CAFTA between the U.S. and Latin American countries; Colombia and Peru; U.S. and Chile; U.S. and Peru; and the Trans-Pacific Partnership (TPP).

THE **TLC** BETWEEN **MERCOSUR** & THE **EUROPEAN** **UNION**

Today, the EU is the first commercial partner of Mercosur. In 1995, both parties signed the Interregional Framework Cooperation Agreement. In 2000, both parties started to negotiate the EU Mercosur Association Agreement, consisting of three chapters: cooperation, trade, and political dialogue. The goal was to negotiate a full trade agreement that does not limit to the trade of industrial and agricultural goods; it would also include services, public tenders, intellectual property and borders, as well as facilitating trade and technical obstacles to trade.

During the last decades, "new generation" FTAs have included rules of liberalization, deregulation and protection of the medicines market which are much more ambitious than the ones agreed on the multilateral entities that regulate in the matter -the WHO and the World Intellectual Property Organization (WIPO).

These FTA negotiations have been delayed for many years due to the different positions of both parties on development and intellectual property. However, since 2016, the Argentinian and Brazilian governments have expressed their interest in signing the agreement without delay.

WHICH WOULD BE THE **IMPACT** OF THE **UE MERCOSUR** AGREEMENT FOR **HEALTH?**

Even though there is no official study carried out by governments to measure the impact FTAs would have on access to health, Fiocruz¹ from Brazil and FGEP² from Argentina made studies to analyze the impact of FTAs on all medicines for HIV and Hep C.

After analyzing the agreement, FGEP³ identified three TRIPS-Plus measures that may affect access to medicines in Argentina:



Exhaustion of intellectual property rights: The EU proposal would limit the possibility to acquire generic medicines at lower prices through the restriction of parallel imports.



Patent Extension: Possibility to extend the term of validity of pharmaceutical patent due to delays on administrative procedures to obtain trading authorization.



Data Exclusivity: This measure prevents generic manufacturers to register its products by using pre-clinical or clinical trials⁴ data already filed by originator companies to obtain commercialization of medicines.

1 Impact assessment of Fiocruz: <https://bit.ly/2Mo9QZg>

2 FGEP's impact assessment in Spanish: <https://bit.ly/2ylcqHs>

FGEP's impact assessment in English: <https://bit.ly/2KbNBsY>

3 This analysis focused on the legal text proposal about "intellectual property rights" carried out in the frame of the exchange of offers on May 11, 2016 by the EU to Mercosur.

4 In other FTAs, the EU agreed a period of 10 years.

The analysis about the impact on public purchases of antiretroviral and Hep C medicines was undertaken through a FGEP's adaptation of the Intellectual Property Rights Impact Assessment (IPRIA) model, developed by the International Center for Trade and Sustainable Development (ICTSD)⁵.

In this sense, it was created a set of 17 antiretroviral and DAA medicines, which are included in the National AIDS and STDs Program (NAP&STDs) vade mecum.

We used a simulation model that allows evaluating the impact of the Intellectual Property Regime changes on access to medicines.

During this simulation, we calculated the impact as the difference between the "status quo scenario" (per year) and alternative scenarios related to different modifications in the Intellectual Property Regime (per year).

Scenarios resulting from the simulation are the following:

- ☑ **"Status Quo Scenario" (SQS):** The status quo is established in the Patent and Inventions Law (Law 24.481 and complementary rules), and grants 20 years of exclusivity to the patent owner, the same period indicated in the TRIPS Agreement. With regard to the protection of data exclusivity that is not in force in Argentina, it is established a period of 0 years of exclusivity.
- ☑ **"Scenario of Patent Extension" (SPE):** Considers the additional protection established in the intellectual property chapter proposed by the EU, estimated to be a two years period.
- ☑ **"Scenario with Protection of Data Exclusivity" (SPDE):** Since the proposal does not specify a period, it was considered 10 years of exclusivity, as negotiated by the EU in other FTAs.
- ☑ **"Full Exclusivity Scenario" (FES):** It combines the SPE and SPDE alternative scenarios. Namely, it considers the additional protection of 2 years and the protection of data exclusivity (10 years).

⁵ Rovira, J.; Abbas, I. y Cortés, M. (2009), "Guide to the IPRIA (Intellectual Property Rights Impact Aggregate) Model", ICTSD, Working Draft, December.

MAIN FINDINGS

OF THE IMPACT ASSESSMENT

If we forecast results to 2050, we can see that:

- ☑ The implementation of TRIPS-Plus measures proposed by the EU to Mercosur will have a *strong impact on investments in antiretroviral and DAA medicines for Hep C* made by the Ministry of Health and on access to health in Argentina.
- ☑ In the case of full exclusivity, by 2050 the State will have to pay *30% more for the same medicines, due to extension of data exclusivity and monopolies.*
- ☑ If the agreement had been in force during 2016, the Ministry of Health would have paid 1075 million pesos to acquire only six (6) medicines –four (4) antiretrovirals for HIV and two (2) antivirals for Hep C– protected by patents. This amount is higher than *half of the total annual budget of the NAP&STDs to purchase more than 60 medicines and to finance prevention and diagnostic activities, among others.*

✔ In the scenario of data exclusivity protection: Additional investment would occur in the first year of entry into effect of the agreement and it would increase gradually. This is not only because of the increase of exclusive medicines, but also because of price increase. By 2050, the additional expenditure of the NAP&STDs would be 26.5% higher than in the status quo scenario.

✔ In the scenario of patent extension: Effects in terms of additional investment would be noticeable by 2041. Increase of investment in medicines by the NAP&STD would be 4% more by 2050.

TRIPS-Plus measures limit access to medicines:

- ✔ They destroy healthcare, judicial and economic sovereignty of countries.
- ✔ They block and impede the manufacturing and trade of medicines, vaccines and generic medical products.
- ✔ They prevent access to affordable generic medicines.
- ✔ They violate the right to health.
- ✔ They enable companies to establish extortionate prices.
- ✔ They prevent governments from fulfilling their obligations of medical assistance.



Governments **must** implement mechanisms to improve the functioning and transparency of their patent systems. They must also reject all the agreements that extend intellectual property rights and restrict the capacity to protect Public Health.

Civil Society **must** promote the introduction of Health Safeguards and the use of legal tools available in the national legislation to **avoid the granting of pharmaceutical patents** that do not meet the patentability requirements.

In addition, organizations **must report pressures** and extortionate practices of pharmaceutical companies that attack Public Health. They should also warn and provide evidence to governments on the negative impact of public policies on Access to Treatment.

All sectors **must** work together to create alternatives of R&D models for the development of health technologies in order to meet the Health need that the patent system does not address.

Picture: José Luis Schanzenbach



Picture: José Luis Schanzenbach

PEOPLE SUMMIT

As a strategy to *develop the organization and articulation* during 2016, FGEP and RedLAM have been part of the convergence of organizations led by the Assembly "Argentina better off without FTA," which gathered organizations that work on topics affected by the commercialization of social goods and the liberalization of trade, such as agriculture and agricultural producers, feminist and Indian organizations.

As a result of such articulation, in December 2016 it was held the *"Peoples' Summit: Building Sovereignty,"* where we discussed topics related to the creation of alternatives that prioritize peoples' rights. FGEP and RedLAM coordinated the *Sanitary Sovereignty Forum*, where more than 50 participants discussed the current situation of public health and the impact of extending intellectual property as promoted in the FTAs. The activity closed with a mobilization in which more than 400 000 people participated with different causes to promote.



Pictures: Emergentes





This work was carried out by the Program on Access to Medicines of Fundación Grupo Efecto Positivo (FGEP). This is the systematization of a 4 year work (2014-2017) around the project "Access to medicine for people living with HIV in middle income countries," as part of the consortium Make Medicines Affordable, coordinated by the International Treatment Preparedness Coalition (ITPC Global) and composed by Fundación Grupo Efecto Positivo (FGEP) from Argentina; Associação Brasileira Interdisciplinar de AIDS (ABIA/GTPI) from Brazil; AIDS Access Foundation from Thailand, Ukrainian Network of People Living with HIV and the Initiative for Medicines, Access and Knowledge (I-MAK).



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