Access to highly effective hepatitis C treatment in Portugal
A Community Perspective

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Summary

This document presents a case study of community engagement for highly effective hepatitis C treatment, led by the Grupo de Ativistas em Tratamentos (hereafter GAT). It demonstrates the process of price and reimbursement negotiations in Portugal and lessons learned in advocacy for universal (or as close as possible) access to these and other life-saving drugs.

In several meetings with all stakeholders, the community engaged with government and the pharmaceutical industry to ensure that key community demands were on the agenda. This dialogue was possible thanks to the long-standing engagement of GAT. And active participation was possible due to the commitment of people in the organization and activists living with HIV and HCV who are committed to advance access to treatment and human rights for People Living with Hepatitis C (PLHCV).

Due to the high financial impact of these processes it was important to ensure access advocates were well experienced and able to effectively cooperate throughout the negotiations

Community empowerment was a key element of GAT’s advocacy efforts. Empowerment included increasing the literacy levels of PLHCV, especially people who use drugs; raising awareness about the availability of these new options; and making sure that everyone knew that they had the right to access treatment, sooner or later, depending on the outcome of the negotiations. During the process several people publicly announced (via social networks and media interviews) that they were living with HCV. This gave reality to the problem in the media and public opinion: a large number of people need a medicine that exists but is not available to them due to its cost.

An evidence-based advocacy framework and the presence of experts from different fields were essential. The approach involved PLHCV, specialist clinicians, hospital administrators, academics, media contacts and decision makers. A key message from the community was, and is, that the price to pay for innovation must be reasonable enough to allow for the implementation of public health interventions in treatment.

Unfortunately, the process of price negotiation came at the cost of transparency, as final prices are not public. However, the experience indicates that for a country with limited resources, negotiating within the existing financial framework, with ambitious objectives in mind, can yield practical results.

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Case study of community involvement in promoting access to DAA’s in Portugal

1. What was the situation of the country regarding Hepatitis C at the start of the negotiation?

   **Hepatitis C prevalence**
   - 50,000 to 100,000 people were estimated to be living with Hepatitis C;²
   - Only 14,000 were being followed in the National Health System (SNS) in 2014. This was the number included in the agreement as a target for treatments that would ensure the lowest price within the cost/volume agreement.
   - High prevalence in People who Use Drugs (PUD) – estimated over 80%³

- Non-national studies also show high prevalence in prison settings.  

Community advocacy
- In 2012, the community started to inform authorities about forthcoming new Direct Acting Antivirals (DAAs) to prevent widespread use of second-generation Protease Inhibitor regimens, which presented only small gains for a limited amount of time (until DAAs were available).
- From 2014, when the first DAA was approved for use in the EU, the community advocated for rapid and universal access to these new regimens. (Advocacy continues as some combinations are not yet available.)
- The community worked simultaneously on improving prevention and screening programs, reducing stigma and discrimination of key groups and increasing the literacy of PLHCV.

2. How did the negotiations proceed?

Negotiations between the government and Gilead began in January 2014 and a deal was announced on 6 February 2015. The agreement was signed on 17 February 2015. Several meetings were held throughout the process on seven consecutive proposals. The Portuguese national Regulator for Medicines noted in a presentation in Sitges, Spain, in 2015 that there have been “numerous meetings (sometimes more than one a week) to discuss and to negotiate the various proposals” since the endpoint was “to get an agreement that would guarantee access to the largest number of patients and ensuring the sustainability of the national health system”.

Chronology of negotiations and medicines included
1st proposal: 16 January 2014 (Sovaldi)
2nd proposal: June 2014 (Sovaldi)
3rd proposal: October 2014 (Sovaldi)
4th proposal: 27 January 2015 (Sovaldi + Harvoni)
5th proposal: 29 January 2015 (Sovaldi + Harvoni)
6th proposal: 5 February 2015 (Sovaldi + Harvoni)
7th proposal: 17 February 2015 (Sovaldi + Harvoni)

Throughout the process, the community:
- Mobilized patients to create public pressure on official authorities;
- Held regular meetings with industry and governmental stakeholders before and throughout the negotiation process to ensure that access at an affordable price was at the top of the agenda (2013 until today);
- Met and communicated with all relevant stakeholders (other civil society organizations, patient organizations, specialty doctors, hospital administrators, academia, scientific societies, among others);
- Issued press releases and public statements (national and European), e.g., first public call to action in July 2014, on World Hepatitis Day;
- GAT broke relations with industry in November 2014 after lack of progress in negotiations and resigned from all formal representations in state-led agencies (December 2014);
- Ensured media coverage to raise Hepatitis C on the general public’s agenda; and
- Increased treatment literacy of PLHCV and People who Use Drugs (PUD).

3. What were the community treatment-related demands?

1. Universal access to treatment

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4 http://ionline.sapo.pt/412100
5 http://tviplayer.iol.pt/video/573cd4a40cf273cab4615328
7 Presented by INFARMED (Portuguese National Regulator) in Sitges VII meeting: Hepatitis C Treatment from the pipeline to real life, 2015
2. Sustainable cost for the health system
3. Leave no one behind (people in prison, people who use drugs, undocumented migrants, etc.)
4. The price of innovative treatment must not come at the cost of other effective public health interventions
5. Immediate treatment for people at risk of progressing to advanced disease immediately with the best interferon-based regimens available
6. No one in a life-threatening situation can be denied treatment, as long as the life expectancy is greater than 12 months (available treatments were not effective on people with very advanced liver disease)
7. Compassionate access programmes to ensure early access to adequate treatment options until the completion of negotiations
8. National health authorities to plan for the use of these new health technologies

4. What were key points of agreement?  

1. The average cost of treatment with a progressive ranking (cost/volume)
2. Same price for 3-month or 6-month treatment courses
3. Payment is per patient treated (cured-SVR) – «pay per performance»
4. Last treatment cost applies to all treatments (the price of each treatment becomes lower the more people are treated, in pre-agreed intervals. The final price – which will be the lowest – retroactively applies to all treatments
5. Previous exceptional authorizations are part of the agreement (payback of excessive price)
6. Centralized funding programme for National Health System hospitals, dedicated to hepatitis C
7. Creation of a Committee responsible for monitoring implementation of the agreement

5. Who can access treatment?

Everyone accounted for in the National Health System can access treatment. However, priority criteria were identified for F3 and F4 patients, patients co-infected with HIV or who present extra hepatic manifestations, as well as people who belong to groups where transmission rates are higher.

However, people who use drugs and people in prison face barriers in accessing treatment, as well as in accessing the healthcare system itself. Moreover, treatment for hepatitis among undocumented migrants is not ensured by the current legal system, as it is for HIV and other infections that are considered to endanger public health, such as tuberculosis.

6. What results are available from the access program so far?

By 9 August 2016, 8,248 persons had started treatments. From information received from the hospitals, 3,340 people had successfully been cured, and 130 had completed treatment but had not been cured. 25 The registry allows for in depth data analysis, but this data is not yet published.

7. What are the limitations of the current agreement? What other things should be considered when thinking about treatment access?

- Few combinations were available at the time, so the agreement foresees the reimbursement of only one drug (Sofosbuvir), and one combination (Sofosbuvir and Ledipasvir).
- Currently, a new deal has been signed that ensures access to another regimen (Abbvie’s 3D) for people with renal impairment or PLHIV with ARV regimens that can interact with Sofosbuvir-based regimens. Other regimens may

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8 Presented by INFARMED (National Regulator) in Sitges, 2015 – presentation attached
become available as new agreements are signed. This may limit usage of optimal combinations for some patients, but should not endanger the majority of treatments. Ideally all combinations would be available and clinical criteria would lead the prescription decision.

- Treatment for people with Genotype 3, especially cirrhotic patients, is limited to Sofosbuvir with Ribavirin for 3 months, or Sofosbuvir with both Ribavirin and Interferon for 6 months. Availability of Daclatasvir for G3 patients, especially with advanced liver disease would be desirable. Currently Daclatasvir is only available through special authorizations of use, a more complex and lengthy process, with additional costs.

- The current deal was also signed with the objective to treat the number of people that were in the National Health System (SNS) when the evaluation of PLHCV in medical follow up was made (2014). An update on the number of people being followed should be done and new agreements should update this number.

- Despite the recent creation of a National Programme for Viral Hepatitis (in 2016), the rapid testing response in terms of HCV testing is led by the community (with inherent limitations). In prisons, people are tested but many do not access treatment\(^9\) (only 150 people out of 2035 diagnosed individuals in prisons had started treatment in May 2016).

- Access to treatment for people who use drugs is hampered by stigma and discrimination, even from health professionals (which varies dramatically from hospital to hospital).

- Difficulties in referral to medical follow-up from both community structures and addiction treatment services persist.

- A more systematic limitation is the fact that it is a national agreement that is confidential; this raises issues that should be addressed more broadly regarding the transparency of the pharmaceutical expenditures and the whole sector.

- Treatment is more than having access to the pills: an integrated response is required. For those with limited or no resources, going to appointments is a challenge, as is adherence and consistent monitoring. The system would benefit from a more thought-out approach to the concept of “treatment access”.

- A universal access program should integrate a scale-up of prevention, testing, linkage to care and support in terms of literacy, adhesion and retention.

8. Lessons learned and points to bear for community/patient groups wishing to engage with national negotiation.

To support your case:
- Have an overview of data and missing data on the hepatitis C situation in the country.
- Use scientific evidence to back the claims that are made, in addition to economic and public health arguments.
- Stress that intervention must be based on evidence and advance both human rights and public health.
- Use the recommendations of international organisations like those emerging from UN bodies. This will help generate support in the most informed part of society, outside of government and industry. It may help inform the less informed part of society about the matter, and increase mobilization. Increasing knowledge about the public health problem that HCV represents can help make a case for governments. The economic impact of not addressing Hepatitis C is well documented internationally, and should be known nationally.

To engage with the decision-making process:
- Have a good understanding of the decision-making process, as well as technical, financial and political factors influencing it.
- Ensure transparency and independence of your group from both governments and industry is paramount.

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- **Ability to pressure both payers and the industry is essential.** Asking payers to commit to provide universal access to the best treatment options, and to the elimination of HCV and the industry to ensure affordable prices that do not endanger the health system should be the minimum.

- **Do not assume government officials are aware of everything.** Informing governments (and other relevant stakeholders) about their options may also contribute to increase their negotiation capacity, as well as the simple fact that civil society and patients are on their side. It can also lead to better recognition of the role of the community in these processes.

- **Build constructive dialogue with governments, regulators, doctors and other health experts** (epidemiologists, health economists, etc.) as well as scientific societies can provide a platform for both consensus or multi-stakeholder pressure groups. This requires extensive work and dialogue capacity from the community, and building capacity in this area, as well as creating a contact network with all these stakeholders can be determinant in several processes.

- **Decision makers** in most countries **tend to listen to the opinions of public health institutions, epidemiologist, scientific societies, among others**. These actors can determine the positioning of the payers in the negotiation processes.

- **Media can potentially be allies of great relevance if public positions are well structured.** Health and lives are prone to media exposure, so good media relations can be a leverage to keep the issue in the public agenda.

- Both governments and industry care about the public image: a vocal community and good media coverage can help up the pressure for solutions.

- Community must **be mindful that industry can also leverage media and community pressure to push for faster negotiations,** which can lead to less favorable agreements. Sustainability of systems and affordable prices must be a priority.

What to ask for?

- **Universal access as a goal** and bearing in mind that it will not always be possible to achieve in the short term. **Intermediate solutions may benefit patients more in the short term.**

- **Sustainability of systems and affordable prices must be a priority.**

- **Negotiating progressive plans or prioritization can help reach a working agreement.**

- These negotiations may be harder in smaller markets, but **international provisions on Intellectual Property rights (TRIPS) are an option to consider should companies not be willing to negotiate,** and their use to ensure access to medicines is defended by WHO\(^{10}\), UNAIDS\(^{11}\), UNDP\(^{12}\) and the UN High Level Panel Access on Access to Essential Medicines whose recommendations were endorsed by the UN Secretary-General in 2016.

- With the changing landscape of new drugs being introduced in the market for the treatment of Hepatitis C, it is very likely that competition itself will significantly decrease prices over the next years. However, many cannot wait, and compassionate access programs can contribute to accelerate access to treatment of people who cannot wait for negotiations to end.

- Agreements must have the future in mind. Whatever the deal is today, **revisions and adjustment periods should be an important part of the negotiations,** since two years from now the scenario will be quite different than it is today.

- **Encouraging the participation of PLHCV and the most affected groups** is very important to help design policies and suggestions that contribute to the reduction in incidence, the increase in people that know their HCV status, and the willingness of PLHCV in adhering to treatment.

- **Developing interventions to reduce stigma and discrimination and facilitates access in key groups.**

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\(^{10}\) [http://www.who.int/bulletin/volumes/91/7/13-115865/en/](http://www.who.int/bulletin/volumes/91/7/13-115865/en/)

\(^{11}\) [http://www.unaids.org/sites/default/files/media_asset/IC2360_DOHA%2810TRIPS_en_0.pdf](http://www.unaids.org/sites/default/files/media_asset/IC2360_DOHA%2810TRIPS_en_0.pdf)

\(^{12}\) [http://www.undp.org/content/dam/undp/library/hivaid/Using%20TRIPS%20Flexibility%20to%20improve%20access%20to%20HIV%20treatment.pdf](http://www.undp.org/content/dam/undp/library/hivaid/Using%20TRIPS%20Flexibility%20to%20improve%20access%20to%20HIV%20treatment.pdf)