SALUD por DERECHO
Right to health foundation

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HEPATITIS C CURE: ACCESS DENIED

BUDGET ISN'T THE PROBLEM, PRICE IS.

• Facing a global Hepatitis C pandemic affecting millions of people in Europe and worldwide and further to the outrageous prices charged by the pharma industry for a cure, a global movement has developed to ensure universal, affordable access to treatment.
• The current crisis around HepC treatment is only a symptom of a sick R&D system based on profit maximization rather than global health needs. Access to medicine is put in jeopardy, either because drugs or treatments do not exist or because patients and national health systems cannot afford the high prices induced by a system based on two-decade-long monopolies.
• The Spanish government has deliberately chosen not to use the solutions at its disposal at the national and European levels to ensure affordable treatment to people living with HepC.
• We must learn from our past experience with the HIV/AIDS to provide a global, more effective and quicker response to these major health challenges.

Global activism for a global pandemic: health isn't for sale!

• Unlike the industry in pricing negotiations, Hepatitis C (HepC) doesn't recognize borders and has spread up to a global pandemic level. Over **180 million people worldwide are infected with HepC**, including about **4 million in Europe** alone. In Spain, between 700.000 and 900.000 people are currently living with the virus. With no vaccine available, **treatment is the only option to bring this pandemic under control and eventually eliminate this disease.**

• The development of highly effective therapies – with up to 95% cure rate - such as sofosbuvir-based therapies - has opened the path for such an action but the **outrageous price** charged by the pharmaceutical industry is keeping HepC elimination out of reach in both developed and developing countries.

• Under the current price offered by Gilead – the patent holder for sofosbuvir, providing this drug to all those who need it could **bankrupt all European health systems**. Additionally, as the American example shows, sofosbuvir's competing treatments currently in the pipeline or under review for approval won't be marketed at a much lower price: companies only agree to discount prices in exchange for higher quantities sold, thus securing a fixed revenue for each country.

• Recent studies have shown that Sofosbuvir could be **produced for about €100 per 12-week course** - far less than the prices Gilead offers under its licenses to developing countries or bilateral negotiations with healthcare payer.

Without generic competition, HepC treatment will remain a luxury our health systems won't be able to afford.

Sofosbuvir, silver bullet or golden pill?

SELECTED COUNTRIES	GENERIC COMPETITION ALLOWED	PRICE OFFERED BY GILEAD PER 12-WEEK TREATMENT
US	✗	$84.000 (€61.000)
GERMANY	✗	€41.000*
UK	✗	£ 35.000 (€46.000)
FRANCE	✗	€41.000
SPAIN	✗	€ 25.000
BRAZIL	✗	$7.000 (€5.000)**
EGYPT	✓	$ 900 (€ 660)
INDIA	✓	$ 900 (€ 660)

* Discounted price agreed with the Government Health Insurance (GKV)
** Latest estimates available from civil society

The symptom of a sick system R+D

• The current crisis around HepC treatment is **only a symptom of a sick R&D system based on profit maximization rather than global health needs.**

• The system is **biased towards sale forecasts, leading to waste of R&D funds and lack of innovation in the fields with major global health impact but little financial returns**. The recent crisis around the Ebola epidemic, a disease known for almost 40 years, has shown that R&D goes where sale is ensured rather than where people need treatments. The diagnosis isn't better when looking at other major pandemics. Treatment for tuberculosis, a disease that claims 1.7 million lives per year, has remained basically unchanged for

More than a one-off solution, universal access to affordable medicines will require deep systemic changes.

decades. After more than 30 years of research, there is still no vaccine for HIV/AIDS. While resistances to antibiotics are spreading, our current arsenal to fight them is decades-old, with almost no new drug in the pipeline.

• Although medical research is heavily financed or carried out on public funds, **the final products usually end up as private monopolies thanks to a patent system aggressively defended by the industry**. With no competition to regulate the price of the end-product, the latter is usually based on negotiation powers and how much the market can bear rather than the actual R&D cost of the patented product or its health benefits.

Hepatitis C treatment is an emblematic example of the R&D system's failures

• R&D costs have been heavily supported by public funding and carried out by public research institutions – thus, reducing the risk and investment carried out by private investors.

• Gilead is said to have bought the startup that owned this drug 3 years ago for **$11 billion**.

• For 2014 alone, Sofosbuvir-based therapies have generated **$12.4 billion** in sales. Under the current sales forecast, Gilead's acquisition may be recovered within a few of years.

• The standard duration for a patent is 20 years.

The Government shouldn't look the other way

1. Systemic changes are the only way to achieve sustainable change in the long run

In the meantime, "Paying or dying" aren't the only options. Putting more money on the table or providing some kind of quick-fix "emergency" funding to cover these unrealistic prices will only feed the problem and strengthen the industry position rather than ensuring access to treatment. Like its European counterparts, the Spanish government has deliberately ignored the options it has at its disposal to achieve **significant price reductions and challenge the pharma industry's monopoly**, thus ensuring the affordability of HepC treatment to its citizens.

2. Cutting HepC drug prices at any costs

To face immediate challenges, the **European Union offers a unique arena for cooperation in order to increase countries' power and weight in price negotiations with the industry**. Secret bilateral deals may appear as a solution to obtain discounts. However, the strategy adopted by the industry for HepC drugs shows that a **united front in Europe will force significant price reduction** until more sustainable measures can be taken.

The knowledge on sofosbuvir-based therapies' actual cost and on Gilead's pricing strategy is there for European countries to build a negotiation strategy based on affordability. The tools for such a negotiation are already available: just few months ago, 20 countries incluiding Spain have agreed on a joint procurement initiative in case of pandemics while other enhanced cooperation initiatives have been put on the table of the Council of the European Union in 2014.

3. Breaking the monopolies by supporting generic competition

Compulsory licensing is allowed under Spanish law and can be implemented to suspend Gilead's and other companies' monopoly over HepC treatment within the next few years. **Spain has a generic industry and so do its European neighbors**. Besides, under international law, all of them have full legal competence and autonomy over when and why a compulsory license can be granted (for further information, see Salud por Derecho's Compulsory Licensing in a Nutshell paper).

Spain has allocated €125 million for these new HepC drug so far. Even if this budget was allocated to provide Sofosbuvir monotherapies to the 700.000 people living HepC in Spain – bearing in mind that not all of them may actually need this type of treatment – the cost treatment per person (about €180) would still be above the €100 production cost of Sofosbuvir calculated by independent studies. If Sofosbuvir can be produced for €100 per person, why should we pay €25.000 for it?

Finally, the patents over sofosbuvir have already be denied or successfully challenged in Egypt and India over the questionable "novelty" of the drug. The European Patent Office – where these patents have been filled for the whole region – does offer possibilities to challenge those patents. **"No patent" will break Gilead's and others' monopolies over the HepC drug market and open it to generic competition.**

With Hepatitis C elimination within our reach, national, European and global health authorities cannot afford to repeat the same mistakes as with HIV/AIDS 30 years ago. Urgent and courageous choices are needed now in order to ensure universal and sustainable access to affordable medicines for HepC and other major pandemics. Let's work towards the fulfillment of the right to health now!