

MARKET ANALYSIS OF NEW-GENERATION MEDICINES FOR HEPATITIS C

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1. OBJECTIVES

- ✓ To reflect the current situation of the market of medicines for hepatitis c and analyze the facts which have occurred under an economic point of view.
- ✓ To identify the three different players (patients, payers and industry) in this game and understand the drivers of their behavior.

2. INTRODUCTION

2014 was a revolution for the cure of hepatitis c with the appearance of new-generation medicines in the market.

This new medicines, led by Sovaldi, have increased significantly the cure rates of old treatments, reduced side effects and length of treatments and generated a big controversy due to its high prices.

3. KEY ASPECTS

1. The virus of hepatitis c has six different genotypes (genetic structures). Genotype 1 is the most common one in the wealthy countries and the most difficult one to treat
2. There are more than 10 million patients of hepatitis c in these wealthy countries
3. There are three important factors in the treatment of the disease: cure rate, length of treatment and side effects

4. OLD vs NEW TREATMENTS

Old treatments used to be the double therapy, composed of interferon and ribavirin, and the triple therapy, which involves the addition of a third drug: telaprevir or boceprevir. New treatments that came in 2014 were Olysio® and Sovaldi®. The final optimal treatments for hepatitis c genotype 1 patients is the combination of Olysio and Sovaldi in an interferon-free treatment with an effectiveness of around 95%.

Genotype	Treatment	Cure Rate	Interferon?	Duration
1	Double th	< 50%	Yes	48
	Triple th	< 70%	Yes	24-48
	Olysio	80%	Yes	24-48
	Sovaldi	89%	Yes	12
	Sovaldi - Olysio	95%	No	12

5. MARKET ANALYSIS

1. THE PATIENTS

Since the appearance of the new medicines, the patients have been carrying out lots of demonstrations and protests trying to get the new medicines. We can explain their situation by using the concept of utility.

$$U(q_i) = q_i - \beta(q_{max} - q_i)$$

q_i : represents the quality of the medicine taken by the patient
 q_{max} : the maximum quality available in the market
 B : is a subjective factor which reflects the perception of the patient about how good the treatment he receives is taking into account the available treatments.

BEFORE SOVALDI (t-1)	AFTER SOVALDI (t)
$U(old) = q^{old} = q^{t-1}_{max}$	$U(old, \{old, Sov\}) = x'$ $q^{old} > x' > 0$
	$U(Sov, \{old, Sov\}) = q^{Sov} = q^t_{max}$ $q^{Sov} > q^{old} > x' > 0$

Before Sovaldi, traditional treatments got a utility equal to q^{old} , but now they do not receive this utility but a lower one. Why? Due to the factor $\beta(q_{max}^t - q_i)$. The feeling of inequality caused by the difference in qualities reduces the utility perceived by them. This makes them feel discriminated (in greater or lesser extent depending on the individual) and with the perception that they are worse off even though, technically (or medically) speaking, they are in the same situation as before. This simple explanation can help to explain the observed reaction of the patients, their demonstrations and strong efforts pressuring the Government to get Sovaldi and why the topic has become so popular occupying lots of hours on TV.

2. THE PAYER

This group is represented by the Government, and its analysis is divided in two perspectives: the short and the long term.

The short term perspective

What do Governments do in first instance? Differences in costs between old and new treatments.

In the US, a typical 12-week treatment course of simeprevir when used with a total of 24-weeks of peginterferon plus ribavirin will cost approximately \$85,000.

A 12-week course of simeprevir plus sofosbuvir costs approximately \$150,000

That makes a difference of \$65,000 per patient. Multiplied by the 140 thousand patients that are currently being treated in US (and supposes just a 9% of total population infected) we have an increase of \$9,100,000,000. More than 9 billion dollars extra.

The long term perspective

Next thing the Governments will consider is whether the treatment is worth it or not. How can we measure this?

The quality-adjusted life-year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived. It is used in assessing the value for money of a medical intervention. The idea is simple: it consists on multiplying the extra life years after the intervention by the quality of those years. A perfect health would receive a value equal to 1, while a year of life lived in a state of less than this perfect health is worth less than 1.

Many reports have been carried on based on this tool, and almost all of them agree that Sovaldi (and, by extension, all the new generation medicines) is worth it, that means, treating all patients is cost effective.

So Governments find themselves in front of an uncomfortable situation: Sovaldi is cost-effective but they can't afford it.

3. THE INDUSTRY

In 2014, the market was dominated by the combination Sovaldi-Olysio, but in 2015 a new medicine entered the market: Harvoni®. This new drug has the same function as previous combination but in one single pill, and has the characteristic that it was developed by Sovaldi's patent owner Gilead Sciences. Why did Gilead Sciences did such investment if they already had half of the monopoly? Is it really worth it? And how is the market reacting to this new model of competition?

Before Harvoni was launched, the patients faced the following situation: a double monopoly by Sovaldi and Olysio. Both monopolies calculated their prices in an attempt to maximize their profits. However, both drugs have to be consumed together.

To explain the consequences of this double monopoly on perfect complementary goods, let us consider a representative consumer that includes the patient wellbeing as well as the costs of the treatment. This representative consumer will have to consume the same quantity of both drugs $Q_i = \min\{q_s^*, q_o^*\}$. Hence, if the patients need to consume both products, the demand of the composite drug will be

$$Q_T = A - B * (p_s^* + p_o^*)$$

Where Sovaldi (similarly Olysio) will maximize with respect to p_s the profit function:

$$Profit_s = (p_s - c_s)(A - B(p_s + p_o)) - F_s$$

If a single monopolist would be selling the composite drug in the market, then firms will maximize the total profits

$$Profits_M = (p_M - c_s - c_o)(A - B * p_M) - F_s - F_o$$

Solving both problems we reach to the next conclusions:

Sovaldi + Olysio	HARVONI
$p_s^* + p_o^* = \frac{2A + B(c_s + c_o)}{3B}$	$p_M^* = \frac{A + B(c_s + c_o)}{2B}$
$Q_T = \frac{A - B(c_s + c_o)}{3}$	$Q_M = \frac{A - B(c_s + c_o)}{2}$
$Profits_{s+o} = \frac{2[A - B(c_s + c_o)]^2}{9B} - F_s - F_o$	$Profits_M = \frac{[A - B(c_s + c_o)]^2}{4B} - F_s - F_o$

1. Price of Harvoni is lower than the combination
2. The quantity sold of Harvoni is higher
3. The profits for the single monopolist are larger

Double marginalization problem: a firm selling a composite drug will make more profits not only than that of the firms selling one component but also more than both of them together. This provides strong incentives to develop such a composite drug.

CONCLUSIONS

1. The market of medicines for hepatitis c has followed a normal evolution from a double monopoly towards a more efficient form of a unique monopoly. This situation is expected to keep on evolving as long as more competitors enter the market.
2. The origin of the conflict which has made this issue of national interest for the media lies in that all the three players have very different goals and the problem comes when discussing about how much of the new welfare generated should correspond to each part.
3. Thus, we cannot talk in here about victims and perpetrators, but to learn from this process to be able to face problems that will come in the future: the importance of investing in R&D and the necessity of the payers of developing effective forms of negotiation that will balance the value in favor of the patients they represent