

# ISPOR 16<sup>th</sup> Annual European Congress

## Dublin 2 - 6 November 2013

### HOW THE PRICING STRATEGY OF 2<sup>ND</sup> GENERATION HCV DIRECT ANTIVIRAL AGENTS CAN AFFECT THE NUMBER OF TREATED PATIENTS IN ITALY AND THE NATIONAL DRUG BUDGET

Elena Lanati<sup>1</sup>, Dario Lidonnici<sup>2</sup>, Carlo Cammà<sup>3</sup>

<sup>1</sup> 3P Solution, Milano, Italy

<sup>2</sup> MA Provider, Milano, Italy

<sup>3</sup> Section of Gastroenterology, DI.BI.MI.S, University of Palermo, Palermo, Italy

#### OBJECTIVES

To assess the impact of new HCV drugs pricing strategy on the number of potential treated/cured patients and on the Italian Healthcare Service budget, using a simplistic model to design different scenarios for second generation direct antiviral agents (DAAs).

#### METHODS

We calculated the HCV drugs budget and the number of patients in order to set a base case budget, by considering:

a) National Drug Agency (AIFA) values for HCV dual therapy drugs, to assess the number of patients currently treated with dual therapy. This number has been calculated using AIFA data on dual therapy in 2010<sup>(1)</sup> (120 millions €, with average patient cost of 12.000,00 € for interferon+ribavirine): on average, in 2010 there were around 10.000 patients on therapy with IFR, that we considered the base case. Considering AISF guidelines that recommend 4 weeks lead in with dual therapy, we assumed that 40%<sup>(2)</sup> of patients stay on dual therapy (DT), accounting for 4.000 patients, and added patients already in dual therapy for around 1.000 patients.

b) triple therapy (TT) number of patients estimated within AIFA reimbursement agreement: 100 millions € for first year of sales of new DAA (boceprevir-BOC and telaprevir, TVR), accounting for 5.000 patients. Total budget including interferon +ribavirine is 160 millions €.

By summing patients treated with dual and triple therapy, we created a base case which accounts for 210 millions € and 10.000 treated patients, that is by the way less than 1% of the number of potential patients infected by HCV in Italy<sup>(3)</sup>. This budget is even below the first HCV drugs estimate done in 2011 by Maratea et al.<sup>(4)</sup> of 300 millions €.

Table 1

Technology	TT	DT	TOT
Efficacy	70%	40%	
Treated population	5.000	5.000	10.000
Responders	3.500	2.000	5.500
Price per year per patient	30.000,00	12.000,00	21.000,00
Budget impact €	150.000.000,00	60.000.000,00	210.000.000,00

Then, we performed budget scenarios for second generation interferon free DAA, assuming to get 90% SVR rates, on two variables:

- 1) Pricing of second generation DAAs, that are supposed to be more effective than first generation;
- 2) Total HCV drugs budget.

We calculated the number of treated and responder patients, considering only genotype 1 HCV to maintain a comparability between base case and future scenarios with new DAAs.

#### RESULTS

1. In order to forecast what could be the financial scenario for the Italian Healthcare System (SSN), we first assumed to have a stable budget vs base case (210 milions).

In this case, assuming to have a higher mean SVR rate for second generation DAAs (interferon free) vs the first generation, with parity price for the SSN vs current average cost of patient/year (1.A) and a potential 20% premium price (1.B), the number of responders will be in any case higher than with triple therapy, as shown below in Table 2.

Table 2

	Base case	1.A parity price	1.B 20% Premium price
Treated population	10.000	10.000	8.333
Responders	5.500	9.000	7.500
Price per year per patient	21.000,00	21.000,00	25.200,00
Budget impact €	210.000.000,00	210.000.000,00	210.000.000,00

Figure 1



2. The second scenario assumes a price lower than base case, considering to get a higher number of patients to be treated, using the theory of price-volume elasticity, that can be easily applied also to drugs. In this case, of course, the price-volume elasticity implies that to get a significant price reduction a huge increase of volume is also needed, which is the HCV case, if we consider that in Italy only a very limited proportion of patient is treated vs the total number of HCV patients. The price-volume elasticity can be applied also to drugs, if we consider that the average drug development cost is similar (around 1 billions \$ per drug), and the price is set mainly on the population size (ie comparing Onco/rare disease vs primary care drugs).

Then, we assumed to double the allocated budget from payers (420.000.000€) vs the base case and to reduce the new DAAs price by a 20%: in this scenario 2, 25.000 patients would be treated and 22.500 (+291% vs. base case) would be cured.

Table 3

	1. Base case	2. 20% decrease vs Base case
Treated population	10.000	25.000,00
Responders	5.500	22.500,00
Price per year per patient	21.000,00	16.800,00
Budget impact €	210.000.000,00	420.000.000,00

Figure 2



#### CONCLUSIONS

As Italy seems to be the country with the highest number of HCV patients in EU, based on ECDC 2010 report<sup>(5)</sup>, but one with the lowest treatment rate, the Italian SSN should invest an increased budget on HCV treatments, only in view of very high rate of response.

Both payers (higher budget) and pharma companies (lower prices) need to have a conjoint effort in order to get a point of concordance in terms of pricing of new drugs, and then to maximize opportunity for HCV patients to be treated. Payers should invest on HCV budget, ie prioritizing vs other therapeutical areas with lower success rate, and Pharma companies should get flexibility on pricing strategies in view of a significant increase in the number of treated patients.

#### REFERENCES:

1. Primo Workshop di Economia e Farmaci in epatologia WEF 2011. Montilla, Quaderni Sole24 Ore Sanità, giugno 2011.
2. Effect of discounting on estimation of benefits determined by hepatitis C treatment. A. Messori, World J Gastroenterol. 2012 June 21; 18(23): 3032-3034
3. Libro Bianco AISF 2010, www.webaisf.org.

4. Nationwide prediction of future expenditure for protease inhibitors in chronic hepatitis C. Maratea et al. Dig Liver Dis. 2012 Jan;44(1):86-7.
5. TECHNICAL REPORT. Surveillance and prevention of hepatitis B and C in Europe. Stockholm, October 2010. [http://ecdc.europa.eu/en/publications/Publications/101012\\_TER\\_HepBandC\\_survey.pdf](http://ecdc.europa.eu/en/publications/Publications/101012_TER_HepBandC_survey.pdf).



3P SOLUTION s.r.l. MILAN - ITALY  
www.3psolution.it - info@3psolution.it  
+390236631574