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The sofosbuvir case – Lessons learned



Directorate of social security



- Hepatitis C is an important health issue in Europe
- New molecules available are important therapeutic innovations...
- ... but represent also a major threat for health systems expenditures
- These molecules have been of great interest because it forced us to tackle critical questions:
 - International cooperation
 - CEA reasoning
 - Pricing negotiation of breaking innovation



International cooperation

Why a common initiative ?

- In October 2013, France made sofosbuvir available via its early access scheme (ATU)
- We realized very soon the huge impact this drug would have on our health budget
- As the problem was roughly the same in our neighbour countries, we thought that it could be interesting to set-up a common initiative on that question

Molecules available at this time

- In France, during early access schemes (“ATU” and “post-ATU”), including negotiation period, prices are set freely
 - “ATU”: until market authorization
 - “post-ATU”: from MA until end of price negotiation

	Start of ATU	ATU price (ex-factory, per box)
Sofosbuvir	October 2013	€18.667
Simeprevir	Nov 2013	€11.667
Daclastavir	March 14	€13.464

- But, once the negotiation ends, the manufacturer has to pay back the difference between the final list price and the free price

- EPSCO meeting, June 20th 2014:
 - First mention of the possibility of an initiative
 - Idea was to warn the industrials on price escalations
 - 14 MS supported the idea
- WPPHSL, July 15th 2014:
 - Decision to organize experts meetings in Fall 2014
- Expert meeting in Brussels, September 17th 2014
 - 26 MS represented + the EC

- What were our expectations from that meeting?
 - To share the maximum information possible
 - To test whether or not some MS could agree about a maximum list price for sofosbuvir and/or a maximum cost per patient treated
 - To prepare the informal meeting of our Ministers next week
 - To test the feasibility of a common letter to Gilead to ask for a considerable price cut

Brussels' meeting - Discussions

- **Evaluation:**
 - Achieved in most MS
 - According to national HTAs, majority of MS chose to prioritize certain indications or patients subgroups
- **Pricing negotiation:**
 - Ongoing in most MS
 - Some MS legislation prohibit information sharing
 - Shared view : major unprecedented impact on health expenditures
- **Reflection on a common approach:**
 - Proposition : ministers could discuss about the relevance of a common letter to manufacturers
 - Follow-up technical reflection among MS on financing of expensive disruptive drugs.

What happened next?

- Milan, September 21st-22nd 2014:
 - Informal meeting of Ministers
 - Presentation of the Brussels' meeting discussions
 - Some countries pushed for more cooperation and more transparency while others were more cautious
 - Decision to write a common letter to the industrial
- And after that?
 - No other meeting has been planned
 - No agreement has been found on time on the writing of the letter
 - Indeed, a significant number of countries concluded their price negotiations



CEA reasoning

Sofosbuvir and the question of CEA

- In October 2013, France introduced **economic evaluation** as part of its health technology assessment process
- Sofosbuvir has been one of the first drugs concerned by this change
- The particularities of this drug put the cost-effectiveness reasoning under question

Why EE has not been useful in the case of sofosbuvir?

- There were methodological issues that prevented relying on EE in that case
- Furthermore, had the methodology been ok, and the drug been evaluated as efficient, we realized that
 - Efficiency does not take into consideration the population size
 - Two drugs can both be efficient for very different population sizes
 - **When financial sustainability is the issue, budget impact can be at least as relevant as EE**

(And on this particular point, Gilead did not provide any budgetary information)

Is sofosbuvir the end of CEA?

- Definitely not !
- It showed us a very good example of its limits though
- CEA is useful in situations where there is need to make choices (between different interventions => arbitrage)
- A specific drug can be good value for money but it doesn't mean you have to pay prices that will eventually threaten the sustainability of the system.



Pricing of breaking innovation

The present situation in France

- Price negotiations ended

	List price (ex-factory, per box)	Vs ATU price
Sofosbuvir	€13.667	- 27 %
Simeprevir	€11.667	- 40 %
Daclastavir	€13.464	- 37 %

- Overall HepC treatments :

- Expenditures : progressive contribution scheme
- Available only via hospitals internal pharmacies
- Decision to treat taken by a multidisciplinary team of physicians
- Indications limited

HepC progressive contribution scheme

- Objective : ensure a large access to treatment, while limiting the burden of HepC treatments on state finances.
- Mechanism : if social security spending on hepatitis C drugs exceeds a cap defined by parliament, the drug manufacturers will be taxed on the revenue that is in excess of this cap.
- Cap :
 - €450M in 2014
 - €700M in 2015



Learns from this experiment

- Achieved:
 - Need for predictability → horizon scanning enhanced on economic side
 - Evolution of methods → budgetary impact in addition to CEA
- Still under improvement
 - Pricing methodology
ex : need to consider combinations
 - Better stakeholder coordination
ex : Target population and healthcare pathways in order to prioritize certain patients subgroups

At UE level - General thoughts

- We felt that our initiative has sometimes been misunderstood
 - We never aimed at starting common negotiations
 - Our wish was to reduce the price asymmetry and avoid perequation as much as possible
- We were surprised by the interest some MS showed on that initiative but a discrepancy appeared on expectations:
 - Big market MS were interested in information sharing only
 - Small market MS pushed for a real common negotiation (JPA...)
- **Such initiatives are really complicated to set up...**

At UE level - Conclusions

- Really interesting to initiate such a collaboration
- However, the difficulties we faced were important and the more countries are involved, the more difficult it is to find a common ground for discussion
- Will there be other initiatives like this one?
 - We hope yes, considering the upcoming challenges and the will of MS
- **Most of all, if you want collaborations to be fruitful, the most important thing is to agree first on your aims and expectations**



Thank you very much