

MARKETING OF THE FIRST BIOSIMILAR INFLIXIMAB IN FRANCE: WHAT BUDGETARY IMPACT IN THE PUBLIC HOSPITALS OF PARIS?

Bocquet F^{1,2,3}, Fusier I¹, Cordonnier AL¹, Lechat P⁴, Paubel P^{1,2,3}

¹ General Agency of Equipment and Health Products (AGEPS), Assistance Publique Hôpitaux de Paris (AP-HP), Paris, France

² Health Law and Health Economics Department, Faculty of Pharmacy, Paris Descartes University, Sorbonne Paris Cité, Paris, France

³ Health Law Institute, Inserm, UMR S 1145, Paris Descartes University, Sorbonne Paris Cité, Paris, France

⁴ Committee on Medicinal Products (COMED), Assistance Publique Hôpitaux de Paris (AP-HP), Paris, France

Introduction

The world of medicines is currently facing up to radical disruptions. At this time unprecedented patent expirations of expensive branded biologics has created the opportunity for biological copies (i.e. biosimilars) to enter the market. After generics—copies of medicines of a chemical origin—the market of biologics is now opening up to competing ‘copies’ with biosimilars. As was the case with generics 20 years ago, the goal with biosimilars is to guarantee patients optimal access to treatments as efficient and secure as their originators, but at reduced prices. Like several biologic ‘blockbusters’, the costly branded infliximab (Remicade® / MSD or Janssen)—a monoclonal antibodies (Mabs) used in oncology, for inflammatory or rheumatic chronic diseases and in dermatology —has expiring European and American patents. The healthcare payers and hospitals are looking forward to infliximab biosimilars, as the situation has become highly strained regarding health systems funding.

Objectives

To analyze the budgetary impact of different scenarios of tenders between the branded infliximab (BRANDED-INFLIX) and its biosimilars (BIOSIM-INFLIX) that could be implemented in the 37 public hospitals of Paris (AP-HP).

Methods

Data collected:

- Branded infliximab expenditures over the 2012-2014 period in AP-HP.
- 2014 medical information from PMSI hospital database (French medical information system program) to determine for which therapeutic indications the patients were treated with infliximab (gastroenterology, rheumatology, dermatology or others) by distinguishing infliximab-naïve patients (INFLIX-NAÏVE) and infliximab-experienced patients (INFLIX-EXPERIENCED).

Three scenarios have been considered for the budget impact analysis:

- Tender between BRANDED-INFLIX and BIOSIM-INFLIX to list only one infliximab in the hospital drug formulary (HDF) with a hypothetical price discount of 20% (S1).
- S1 but with a hypothetical price discount of 30% (S2).
- Tender between BRANDED-INFLIX and BIOSIM-INFLIX only for INFLIX-NAÏVE and no tender for INFLIX-EXPERIENCED who remain treated by BRANDED-INFLIX with a price discount of 20% and a proportion of INFLIX-NAÏVE treated by BIOSIM-INFLIX of 10% if it wins the tender (S3).

Results

Branded infliximab (Remicade®) expenditures in AP-HP: **€42,1 million in 2014, €38,1 million in 2013 and €33,6 million in 2012.**

Table 1: Patients' profiles treated by the BRANDED-INFLIX in AP-HP in 2014

	Rheumatology	Gastroenterology	Dermatology	Others *	TOTAL
INFLIX-NAÏVE	471 (32.5%)	1.217 (35.9%)	31 (40.3%)	241 (42.8%)	1.960 (35.7%)
INFLIX-EXPERIENCED	980 (67.5%)	2.175 (64.1%)	46 (59.7%)	322 (57.2 %)	3.523 (64.3%)
Total 2014: N patients (% of the total)	1.451 (26.4%)	3.392 (61.9%)	77 (1.4%)	563 (10,3 %)	5.483 (100.0%)

Source: PMSI hospital database



Table 2: Savings generated by S1, S2 and S3 scenarios in AP-HP

Scenarios	Tender outcomes	Time horizon	Rheumatology (million Euros)	Gastroenterology (million Euros)	Dermatology (million Euros)	Others * (million Euros)	TOTAL (million Euros)
S1	BIOSIM-INFLIX or BRANDED-INFLIX	1 year	2.1	4.8	0.1	0.6	7.6
S2			3.2	7.1	0.2	0.9	11.4
S1		3 years	6.3	14.4	0.3	1.8	22.8
S2			9.6	21.3	0.6	2.7	34.2
S3	NAÏVE: BIOSIM-INFLIX PRETREATED: BRANDED-INFLIX	1 year	0.7	1.5	0.03	0.2	2.4
	NAÏVE: BRANDED-INFLIX PRETREATED: BRANDED-INFLIX		3 years	2.1	4.5	0.1	0.6
	NAÏVE: BIOSIM-INFLIX PRETREATED: BRANDED-INFLIX						

* Takayasu's arteritis, uveitis and severe noninfectious Pyoderma gangrenosum and others.

Source: AP-HP



Conclusion

In 2015, the Committee on Medicinal Products (COMED) of AP-HP has taken into account this budget impact analysis in its decision-making process. The COMED has recently decided to implement tenders between BRANDED-INFLIX and BIOSIM-INFLIX in AP-HP but only for INFLIX-NAÏVE patients (S3) because **the current French law does not allow the switch from branded biologics to biosimilars**. A BIOSIM-INFLIX has won the tender in June 2015 and has resulted in a price discount estimated at 45%, which is a gain estimated at around **€ 6 million per year** for AP-HP. In addition, the renegotiation of the BRANDED-INFLIX price has generated **more than € 1 million savings** for the institution. As these results show, the savings generated by further hypothetical tenders with biosimilars in the future will be largely dependent on the scope of the tenders implemented.