BIOSIMILAR HEMATOPOIETIC GROWTH FACTORS IN THE PUBLIC HOSPITALS OF PARIS: TRADE-OFFS BETWEEN ECONOMIC GOALS AND EVIDENCE BASED MEDICINE

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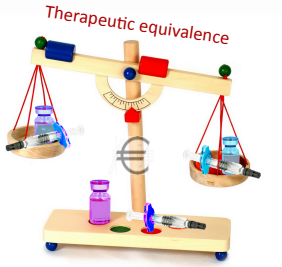
Organization

The decision-making process for drug selection in the **37 hospitals (22,000 beds, 7 million patients each year)** of the Public Assistance – Hospitals of Paris is divided into two successive stages that take place in the General Agency of Equipment and Health Products (AGEPS).

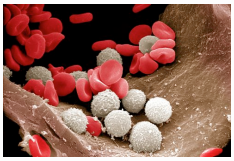
- **The Scientific Assessment:** The Therapeutic Evaluation Unit of the Agency evaluates the product's therapeutic benefits and prepares a scientific assessment report for the Committee on Medicinal Products (COMED). Assisted by boards of experts, the COMED decides whether or not to list the product in the hospital drug formulary (HDF) and whether there should be a competition or not between new drugs and therapeutic equivalents.
- **The procurement process:** After approval these products may participate in the next tender. Then AGEPS runs the procurement process yearly or every two years. This process meets both the patients' needs and compares products allowed to participate in the tender on several criteria. The winning tender should be the one offering the best value for money.



Savings on drug expenditure

Problem or issue addressed

In the current context of limited economic growth and pressures on healthcare, **biosimilars** may represent one of the most lucrative sources of savings on drug expenditure for AP-HP in a few years. After chemical medicines copied as generic, it is the turn of biologics to also approach their own swathe of patent expirations. The complexity of biologics makes it impossible to produce identical copies. **Biosimilars are considered 'comparable' to the originator brand, but this does not ensure that they ~~are therapeutic equivalents.~~**



Biosimilar short-acting erythropoietins (SA-EPOs)

Biosimilar short-acting G-CSFs (SA-G-CSFs)

Arrival on the French market in 2008 and in 2009

Challenge: To specify conditions for a competition between biosimilars and originator brands

Goals

- **To analyse the decision-making process** of the agreement of AP-HP HDF for biosimilar SA-EPOs and SA-GCSFs
- **To evaluate the relative weights of scientific, technical and economic selection criteria** in the procurement process of biosimilars in the AP-HP hospitals.

Outcomes used in the decision

- **Recommendations on EPOs by a board of experts based on:**
  - ✧ Documented evidence on efficacy and safety (Health Technology Assessment Reports, European and national guidelines, Periodic Safety Update Reports).
  - ✧ Analysis of consumption: SA-EPOs/long-acting EPOs (LA-EPOs) ratio for each medical specialty concerned.
- **HTA reports, guidelines for biosimilar SA-GCSFs.**

Results

2009: lack of experience of use and increased immunogenicity risk with biosimilar SA-EPOs → No biosimilar in HDF. **2010:** High degree of molecular similarity between **SA-GCSFs → favorable opinion for competition between biosimilar filgrastim (n=3) and originator lenograstim (n=1). 2011: new safety information available for biosimilar SA-EPOs.** SA-EPOs were almost exclusively used in oncohematology while LA-EPOs were preferred by nephrologists to reduce the number of EPOs injections → **favorable opinion for competition between biosimilar EPO alfa (n=1) and originators EPO alfa and beta (n=2).** LA-EPOs have not been competing with SA-EPOs.

TENDER RESULTS	Short-Acting EPOs (april 2012)			Short-Acting G-CSFs (mars 2011)			
Tender criteria	Biosimilar 1	SA-EPOs originator 1 *	SA-EPOs originator 2 **	Biosimilar 1	Biosimilar 2	Biosimilar 3	SA-G-CSF originator 2 ***
Pharmaceutical criteria (score/65)	46,3	54,8	53,9	56,3	52,4	56,8	30,0
Economic criteria (score/35)	30,2	35,0	26,0	29,8	34,7	33,8	Too expensive
Total score/100	76,5	89,8	79,9	86,1	87,1	90,6	_
Price (€ / DDD)	2,14	1,45	2,50	30,33	14,58	17,50	91,83
Tender results	2nd	WINNER	3rd	3rd	2nd	WINNER	_

* EPO alfa; ** EPO beta; *** SA-G-CSF originator 2 (lenograstim), the originator 1 (filgrastim) has not participate in the tender.

The biosimilar SA-EPO lost the tender due to failure in terms of quality labelling and security of use associated with a higher price compared to the 2 originators. For SA-G-CSF, the biosimilar 3 won the tender but it was not the cheapest among the others.

Conclusion

Even by offering products at competitive prices, biosimilars do not always access the market because originator prices are already low. Moreover, to be selected, biosimilars should present the best compromise between clinical efficacy and safety – that depends on the therapeutic class considered – and technical quality. If some barriers to biosimilars market development are already known, additional barriers related to local requirements and local hospitals practices should also be taken into account. Such issues become even more sensitive with the arrival in 2013 of the first biosimilar monoclonal antibodies in Europe.

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