

TO WHAT EXTENT CAN BIOSIMILARS COMPETE WITH BRAND NAME BIOLOGICS? A EU-5 GRANULOCYTE-COLONY STIMULATING FACTORS MARKETS ANALYSIS

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Introduction

At this time unprecedented patent expirations of expensive branded biologics has created the opportunity for biological copies (i.e. biosimilars) to enter the market. Unlike generics (copies of chemical molecules), as these are proteins produced by living organisms, biosimilars are complex and difficult to produce. Biologics are a powerful driver of pharmaceutical innovation (e.g. in oncology, hematology and diabetes) but represent significant costs to health systems, thereby threatening their accessibility and financial sustainability. In the context of financial crisis, biosimilars could represent an important potential savings for health systems. However, **the knowledge of the factors affecting the competition following patent expiry among biologics remains limited.**

Objectives

- To determine the ability of biosimilars to compete with brand name biologics within the same therapeutic class by **analysing in a descriptive manner the EU-5-GSF (5 main Granulocyte-Colony Stimulating Factors markets of the European Union)** and to categorize them by **dominant distribution models**: Retail market (R), Hospital market (H) or both (R+H).
- To characterize the **factors affecting the G-CSF biosimilar uptakes**, particularly that of **biosimilar prices relative to reference G-CSFs**.

Methods

As of the end of 2011, 14 biosimilars have been approved in the EU: 2 human growth hormones (h-GHs), 7 G-CSFs and 5 epoetins (EPOs).

Selection of countries :

Countries assessed for eligibility (n= 45): 27 EU countries, Argentina, Australia, Brazil, Canada, Cuba, India, Japan, Malaysia, Mexico, Peru, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, Turkey, the US and Venezuela

Countries excluded (n= 38): looser regulatory framework for biosimilars than in the EU; where pharmaceutical firms do always respect intellectual property and countries with a < US\$ 2.5 billion biological market in 2010

Countries selected (n= 7)
EU-5 countries (France, Germany, Italy, Spain and the UK), Japan and the US

Countries excluded (n= 2): with no-G-CSF biosimilar on their national market at the end of 2011

Countries analysed (n= 5)
EU-5 countries (France, Germany, Italy, Spain and the UK)

Fig. 1: Inclusion and exclusion criteria for countries in the study

Results

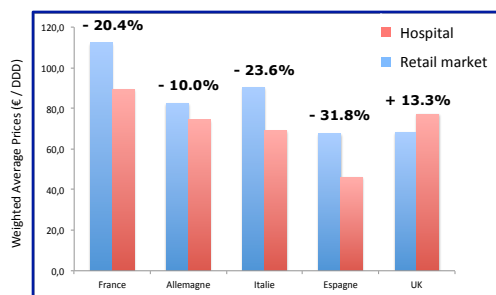


Fig. 3: Biosimilar prices discounts versus originator in 2011

2 G-CSF market profiles:

- Countries with a high retail market distribution which are the largest G-CSF markets and **low global G-CSF biosimilar uptakes (France and Germany)**.
- Countries with a dominant hospital channel which are the smallest markets with **high G-CSF biosimilar uptakes (Spain and Italy)**.

- Selection of medicines:** The h-GHs market is a niche market. The G-CSF and EPO have some:
 - Commonalities: High elasticity of demand and intense competition between branded products (short-acting and long-acting products).
 - Dissimilarities: Fewer manufacturers and products on the G-CSF market, well-established equivalence between short and long-acting G-CSFs doses, EPOs are complex glycosylated molecules while G-CSFs are simple non-glycosylated molecules, immunogenicity concerns following PRCA with an originator EPO in the late 1990s, which is not the case with G-CSF.

- Data source:** Data on medicine volumes, values and ex-manufacturer prices for all G-CSF categories were provided by IMS Health. Volumes were calculated in DDD and price in euros per DDD. In the EU biosimilar G-CSFs benefit from a 5-year experience (from 2007 to 2011).

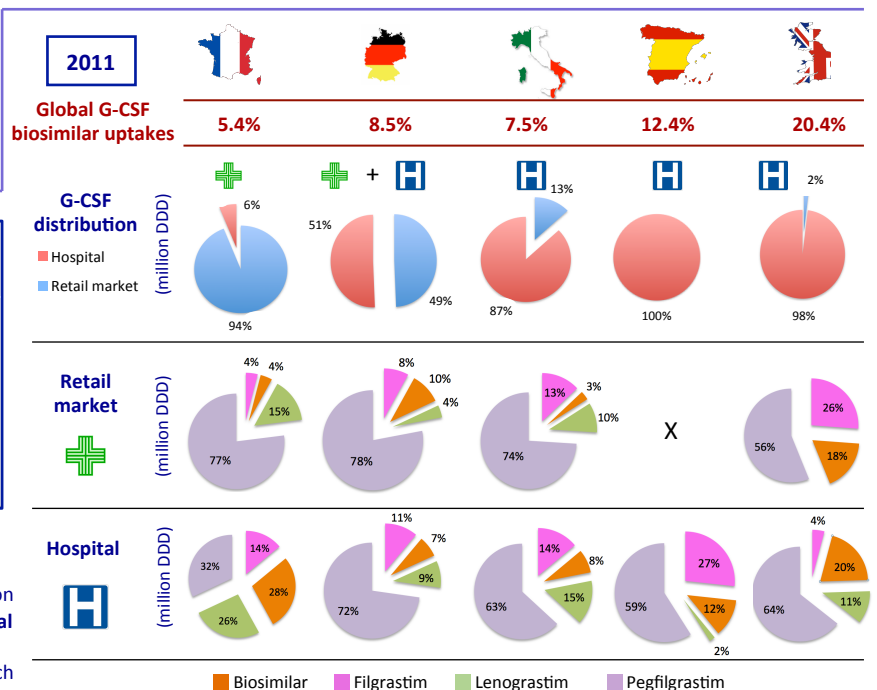


Fig. 2: Characteristics of the EU-5 G-CSF retail and hospital markets in volume (million DDD) in 2011

The G-CSF biosimilar uptakes depend critically on the market access for biosimilars at a local/regional level. The more the decisions are decentralized (hospitals, local purchasing structures) the more their uptakes are high. The price difference between G-CSF biosimilars and their reference plays a marginal role at a global level (+13.3% in the UK and -20.4% in France).

Conclusion

The competition with G-CSF biosimilars varies significantly between EU-5 countries due to distribution channel differences. Currently, this competition is not mainly based on prices, but on local political options to stimulate tendering between them and other most recently branded products. In countries with dominant retail markets, a prerequisite for the success of biosimilars is that governments approve their substitution in the same way generics are authorized by introducing them case-by-case, within a therapeutic class.