Comparison of Biosimilar Reimbursement Policies in the US and Select European Markets

HPR20

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OBJECTIVES

To compare the similarities and differences between the reimbursement of biosimilars in the US and Europe. Biosimilars are medicines that contain a version of an active substance of an approved biological medicinal product with available comparability studies.

METHODS

Regional and national regulatory pathways and system cost-containment measures that affect the reimbursement levels in the US, UK, France, Germany, Italy and Spain were reviewed and compared.

In addition, the time to availably of oncology biosimilar products were compared with a benchmark for non-biosimilar oncology products.

CONCLUSIONS

The regulatory pathways for biosimilar products are faster than for the reference products in the focus markets. In the oncology biosimilar examples considered, in almost all cases reimbursement was achieved more quickly than the benchmark for non-biosimilar oncology. Reimbursement levels in the US are more complex due to the variability in the payer programs both public (e.g. Medicare Part D or the 340B Drug Pricing Program) and private insurers.

ABBREVIATIONS

AIFA: Italian Medicines Agency
AMNOG: Act on the Reorganisation of the Pharmaceutical Market
CEPS: Economic Committee for Health Products
CTS: Comitato Tecnico Scientifico (AIFA scientific committee
EMA: European Medicines Agency
EU: European Union
Leem: French Pharmaceutical Industry Association
NICE: National Institute for Health and Care Excellence

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RESULTS

Across all markets there are processes that facilitate access to biosimilar products.

Regulatory Processes

Regional:

The EMA's scientific committee considers biosimilar medicine marketing authorisation applications for all medicines seeking central authorisation prior to national approval and marketing. The biosimilars are judged to the same standards (quality, safety and efficacy) as all EU-approved biological medicines. Biosimilar manufacturers are required to demonstrate that their biological medicine is highly similar to the reference medicine and that there are no clinically meaningful differences, via comprehensive comparability studies[1].

National:

Following Brexit, the Medicines and Healthcare products Regulatory Agency (MHRA) is the sole UK medicines and medical device regulator.
The MHRA provides guidance[2] to biosimilar manufacturers which requires them to consider the principles contained in the EMA-Committee for Medicinal Products for Human Use (CHMP), it has also enacted some changes. A primary change is that "confirmatory" human trials may not be necessary. The MHRA justification of this approach rests in the fact that a biosimilar which has comparable binding and other relevant functional characteristics to the reference product could reasonably be expected to have the equivalent clinical effect.

The 2009 Biologics Price Competition and Innovation Act[3,4] (BPCI Act) provides an abbreviated regulatory approval pathway for biosimilars.
This pathway allows a biosimilar biological product to be licensed while submitting an abbreviated complement of product-specific preclinical and clinical data, however data are required demonstrating bio similarity to the biological reference product.

National Pricing and Reimbursements

Fast tracking

Within the EU4 and UK there exist fast track processes to negotiate biosimilar pricing compared to the reference product, ranging from 15 days in France to 3 months in Italy (Table 1).
It is often assumed that drugs in the US are immediately available on FDA approval, however coverage and reimbursement decisions take time due to the independent and decentralised nature of US payers.

National discounts

The framework agreement between CEPS and Leem allows for reductions of **30%-40%** for the biosimilar and 20%-30% for the original[5] (Table 1) for the reference product, however at 24 and 42 months post first biosimilar commercialisation further price regulation is established. The higher the reference product market share, the more discount is applied to the biosimilar.

Commercialisation of the first biosimilar will see at least a **15%** discount of the reference product price, with subsequent biosimilars facing a **30%** reduction[6].

For medicines in classes A (innovative, cost effective or essential drugs for chronic and serious diseases) and H (hospital drugs) the costs are completely covered by the health service and the discounts are considerable. They range from **30%-75%** depending on the anticipated sales volume[7].

The discount **20%-30%** is expected for the first biosimilar, subsequent market entrants will face inclusion in the reference price and equal price with the originator based on the weighted average.

Developed a commissioning framework[9] to set the basis for biosimilar procurement.

The 340B Drug Pricing Program (where manufacturers sell discounted outpatient drugs to organisations providing care for low income / uninsured patients). Hospitals in this program receive discounts on the average sales price (ASP) but are reimbursed by Medicare at the same level as non-340B hospitals. These discounts could make the reference product appear more profitable than the biosimilars.

A study by the US Office of Inspector General[10] found biosimilar reference products were prescribed five times more often than biosimilars in Part D. The 2018 Bipartisan Budget Act removed the exclusion of biosimilars from the Medicare Part D coverage gap discount program[11,12]. The **coverage gap discount paid by the manufacturer for biosimilars and branded medicines is 70%**[13].

The CMS has provided separate Healthcare Common Procedure Coding Systems (HCPCS) codes and payment rates for biosimilars to promote a competitive playing field for both reference products and biosimilars.

Table 1: Pricing and Reimbursement

Ex. Manufacturer	The 'Ex. manufacturer price' denotes the initial cost set by the drug manufacturer, excluding additional charges and adjustments incurred throughout the supply chain					
Pricing Regime	CEPS Reference List Pricing	AMNOG Free pricing, Informal Reference List Pricing	AIFA(CTS) Free Pricing	Interministerial Committee Free pricing	NICE Free pricing	CMS / Private Insurers Free pricing
Fast Track Biosimilar Pricing Process	15 days	Almost immediate	2-3 months	n/a	n/a	n/a
Biosimilar National level discount on Reference Product price	40%[5] (Gen pharmacy) 30%[5] (Hospital pharmacy)	15% – 30%[6]	30%-50%[7] Class H products 45%-75%[7] Class A products	20% - 30%[6]	10-25%[6]	Fixed percentage based on the reference ~ 30%[8]

Time to Achieve First Price

Considering the example of the oncology biosimilars reimbursed in all focus countries (Table 2), the time from first approval to the first price being accepted varies widely. Germany and the UK are generally the quickest markets to achieve a reimbursable price.

When compared with EFPIA's Patient Wait Indicator for oncology product availability 2017-2020[10] which excludes biosimilars, in almost all instances the time to reimbursement is substantially shorter for the oncology biosimilars than the oncology non-biosimilars.

Table 2: Time to 1st Pricing and Reimbursement[14]*

Time (days) to Price / Reimbursement						
KANJINTI	91 / 28	44/ 44	108 / 86	117 / 61	14 / 0	144 / -
RUXIENCE	167 / 167	105 / 105	330 / 330	167 / 166	91 / 0	184 / -
Oncology product time to availability[15]	490	100	405	469	268	-

- Oncology biosimilars reimbursed in EU4 and UK and available in US with marketing authorisation between 2017 and 2020)
- Data for lowest dose and pack size available in all countries
- Calendar days from first approval to first price date and reimbursement date
- Time to availability is date from marketing authorisation to reimbursement
- Oncology product time to availability excludes biosimilars
- - represents data not available