PHP106

Are EU Payers Adapting Biosimilar Pricing and Reimbursement Approval Processes to Optimize Healthcare Savings?

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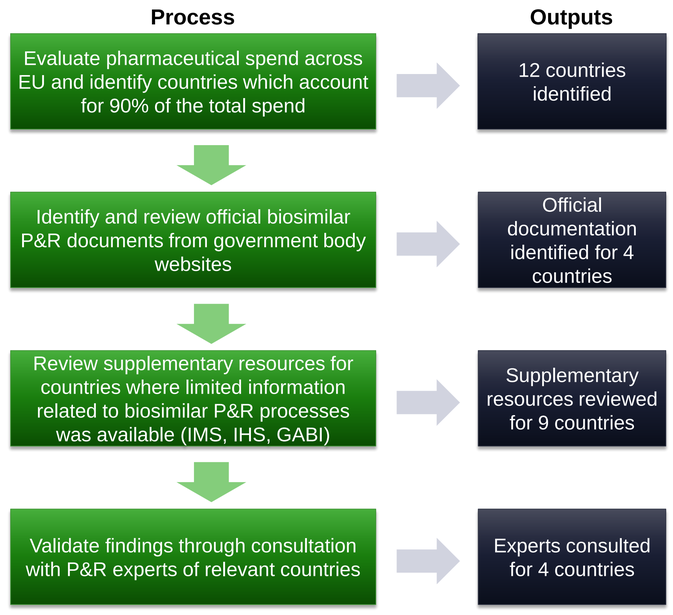
Introduction

- A number of Europe's top-selling biologic drugs face patent expiration in the next 5 years. It has been estimated that by 2020, the emergence of biosimilars will provide healthcare cost savings of between €11.8 and €33 billion across the European Union (EU).[1]
- Since 2006, the European Medicines Agency (EMA) has implemented a centralized regulatory approval pathway for biosimilars, which has facilitated marketing authorisation for biosimilars in the EU.[2]
- However, individual member states are free to develop their own Pricing and Reimbursement (P&R) policies on biosimilars, with the result that the rate of uptake of biosimilars varies widely across Europe.[3]
- In the US, the FDA introduced an abbreviated licensure pathway in 2010 and the first biosimilar, Zarxio (filgrastim-sndz), was approved in March 2015. However, Zarxio has yet to be launched.[4]
- The aim of this study was to determine if EU P&R bodies have revised their approval processes for biosimilar medicines to enable faster access and optimize the potential healthcare savings.

Methods

- To determine markets for inclusion within this study, Organisation for Economic Co-operation and Development (OECD) pharmaceutical spend data across Europe (based on 2012 [or latest available year]) was utilized to identify the European countries that account for 90% of EU pharmaceutical spend.
- 12 countries were identified for inclusion in the study.
- Biosimilar P&R procedures across Europe were analyzed to determine if they differed from the standard and generic P&R processes (Figure 1).
- Documentation from 'official' regulatory, governmental or reimbursement bodies for each country were reviewed for biosimilar P&R information. Search terms such as biosimilar; biosimilar guidelines; biosimilar reimbursement (or local language equivalents) were used to search for relevant documentation.
- Supplementary resources such as the Generics and Biosimilars Initiative (GABI), IMS and IHS, were reviewed for countries where limited 'official' biosimilar P&R information was available.
- If the biosimilar P&R process in a particular country could not be determined P&R country experts were consulted to validate findings.

Figure 1. Project Process and Outputs

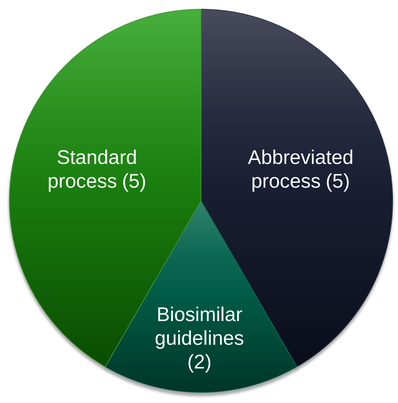


Results

Biosimilar Pricing and Reimbursement Pathway

- Biosimilar P&R pathways were classified as standard, biosimilar and abbreviated (Figure 2).
- Five of the 12 countries reviewed require biosimilars to undergo the standard reimbursement pathway, often requiring submission of comparative clinical data and budget impact and/or health economic models.
- Two countries, Belgium and Switzerland, provide specific guidelines for biosimilar P&R submissions.
- Five countries facilitate biosimilar access by applying an abbreviated approval process, similar to that of generic products.
- A detailed overview of the biosimilars P&R pathways for each market is provided in Table 1.

Figure 2. Countries grouped by biosimilar P&R pathway



Category	Description
Standard process	No identifiable differences from a new branded product P&R pathway
Biosimilar guidelines	Specific biosimilar submission guidelines available as part of the P&R pathway
Abbreviated process	Simplified P&R process, usually comparable to a generic P&R pathway

Biosimilar Pricing Policies

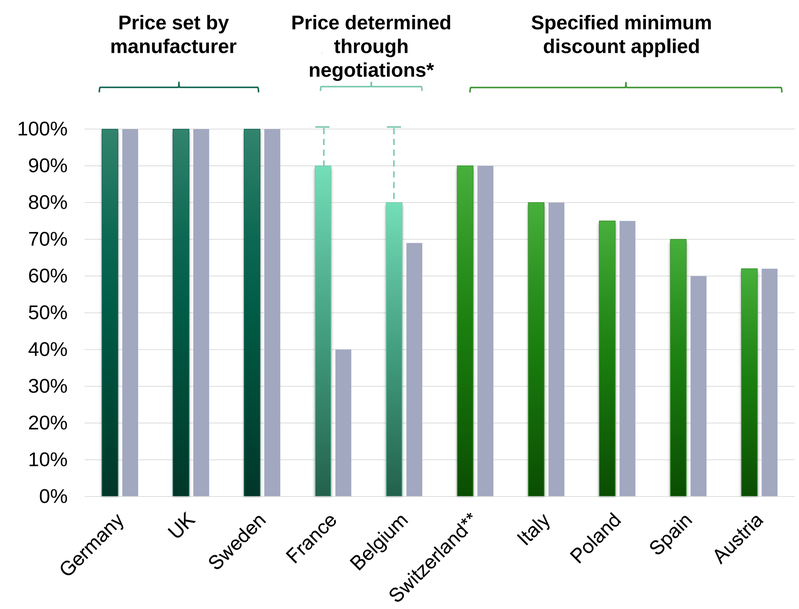
- From a pricing perspective, there is a range of policies applied to price biosimilars:
- In Germany, the UK and Sweden the price is set by the manufacturer but cannot be higher than the branded price (Figure 3).
- Biosimilar prices are negotiated in Belgium and France.
- Mandatory biosimilar price discounts are applied in Switzerland, Spain, Italy, Austria and Poland.
- In Italy, Austria, and Poland the price discount applied is equivalent to that required for a generic product.
- In Greece and the Netherlands, maximum achievable price is based on international referencing pricing.

Table 1. Description of Biosimilar P&R pathway

	Country	Specified Price Discount	Key take-away
Standard process	**France**[5]	N	• Products are reviewed by the Transparency Commission • Biosimilar products will be given an ASMR rating of V, forming the basis of price negotiations with CEPS
	Greece[6]	N	• Reimbursement is determined by the Ministry of Health and Social Solidarity with no dispensations for biosimilar products • Products are priced at the average of the three lowest prices across Europe
	Spain[7,8,9]	Y	• 2014 reform of the reference pricing system includes the creation biosimilar groups however concerns have been raised regarding how this contradicts other biosimilar policy, for example on interchangeability • Biosimilar prices are set 30% below originator product price
	Sweden[10]	N	• For reimbursement under the pharmaceutical benefit scheme, all products are reviewed by the TLV • A cost minimisation model versus branded original is required
	UK[11,12,13]	N	• England: NICE will consider biosimilar products, usually in the context of an MTA • Scotland and Wales: SMC and AWMSG respectively require full submissions for all new biosimilar medicines • Cost minimisation models are accepted
Biosimilar guidelines available	**Belgium**[14,15]	N	• Biosimilar products undergo review for reimbursement by the CRM • Guidelines for biosimilar submissions (filed under class 2) are available • For biosimilar products filed under class 2, list price cannot exceed that of their comparator and is set through negotiations
	Switzerland[16,17]	Y	• Products are reviewed by the BAG for inclusion on the speciality list • Submission guidelines include specific section for biosimilar submissions • Biosimilars are required to have an ex-manufacturer price 10% below branded original to be considered cost-effective
Abbreviated process	**Austria**[6,18]	Y	• All drugs are reviewed for reimbursement by the HVB • Price caps implemented for generic products are applied to biosimilars
	Germany[6,9,19]	N	• Biosimilars do not undergo early benefit assessment by the G-BA • Biosimilars and their originator drug can be included in the same level 1 reference price group (EPO and somatropin are included in the reference pricing system)
	Italy[20]	Y	• Faster access to market (60 days) achieved if a pre-specified price discount, dependent on sales of the reference product, is applied • Otherwise, full AIFA P&R negotiations are required (180 days) and, like generics, biosimilars are required to set their price at least 20% below the originator product price
	Netherlands[9,21]	N	• Zorginstituut Nederland (formerly CVZ) regards biological medicines as therapeutically interchangeable if they have been deemed "similar" following registration by the EMA or CBG • Biosimilars do not undergo standard P&R assessment; they are allocated to same reference price group as originator
	Poland[9]	Y	• P&R approval process for biosimilars is the same as for generics • Mandatory price discount of 25% below originator is applied (if it's first to original)

ASMR: Amélioration du service médical rendu; AWMSG: All Wales Medicines Strategy Group; BAG: Bundesamt für Gesundheit; CBG: College ter Beoordeling van Geneesmiddelen; CEPS: Comité Economique des Produits de Santé; CRM: Commission de Remboursement des Médicaments; CT: Transparency Commission; CVZ: College voor zorgverzekeringen; EPO: Erythropoietin; EMA: European Medicines Agency; G-BA: Gemeinsame Bundesausschuss; HVB: Hauptverband der österreichischen Sozialversicherungsträger; MTA: Multiple Technology Appraisal; NICE: National Institute for Health and Care Excellence: P&R: pricing and reimbursement; SMC: Scottish Medicines Consortium; SGCMPS: General Subdirectorate of Quality of Medicines and Health Products; TLV: Dental and Pharmaceutical Benefits Agency

Figure 3. Maximum achievable biosimilar price as a % of initial originator price



*Theoretically, price may be negotiated up to that of the reference product however in practice a range of discounts have been applied: France - Hospital biosimilar products have been priced at 10% below initial originator product price. Retail biosimilar product prices are expected to range from 25-35% below reference product price; Belgium - negotiated biosimilar prices have ranged from 20-34% below reference product price
**Mandatory generic price discounts in Switzerland can be higher, based on sales of originator product Netherlands and Greece excluded from figure: maximum achievable price is based on international referencing pricing

Limitations

- P&R processes are continually evolving and the introduction of biosimilars over the coming years may trigger the establishment of specialised biosimilar P&R pathways.
- Limited official documentation relating to biosimilar P&R pathways were available.
- The current analysis only reflects official national pricing processes and does not consider local hospital tenders or negotiations, which can significantly reduce drug acquisition cost.

Discussion and Conclusion

- The majority of European countries require biosimilars, unlike generics, to undergo a comprehensive P&R process.
- This finding is aligned with the view that, unlike generics, most EU countries do not consider biosimilars interchangeable to their reference products.
- Completing a comprehensive standard P&R process for biosimilars can be time consuming, resource intensive and costly for both the manufacturers and P&R bodies.
- The implication is that European payers have yet to consider biosimilars to be clinically comparable to their reference products or to fully recognise the potential healthcare savings from having an expedited biosimilar P&R approval process.
- An expedited biosmilar P&R pathway would allow faster time to market access and reduce resources required to undertake biosimilar P&R assessments.

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