Potential Impacts of the EMA-HMA joint statement supporting biosimilar interchangeability in biosimilar access in the EU

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INTRODUCTION

On April 21, 2023, the EMA-HMA published a statement on the scientific rationale supporting the interchangeability of biosimilars, by recognizing their clinical equivalence to originators based on almost two decades of real-world evidence.[2, 3] EMA's official endorsement followed the decision of key government bodies across the EU4 and the UK, who had previously recognized the scientific equivalence of biosimilars and started supporting biosimilar interchangeability. [4,5]

EU4 + UK payers have tried to promote biosimilar uptake in their respective countries with policies fostering a more conducive environment for biosimilars. For example, the U.K.'s MHRA has discontinued the requirement for biosimilars to undergo confirmatory efficacy trials as a licensing condition since 2021[4], and most countries currently allow switching to biosimilars.[8-12]

However, country-specific policies on biosimilar pricing and uptake vary within EU member states and the UK. Thus, biosimilar uptake is not uniform across European markets and also varies at the regional level. Recent policies designed to improve biosimilar adoption centers around increasing incentives towards biosimilar prescribing (e.g., prescribing quotas, financial incentives as a percentage of cost-savings generated) and regulating automatic substitution in some markets.[15]

OBJECTIVES

This research aimed to explore payer perceptions of the EMA-HMA joint statement supporting biosimilar interchangeability in the EU4 (France, Italy, Germany, Spain), and the UK and its potential impact on biosimilar utilization policies.

METHODS

A comprehensive literature review of EMA and country-specific guidance statements on biosimilar interchangeability was conducted across the EU4 and the UK markets. 10 payers (N=2/market) were also interviewed between 03-16 OCT, 2023 to assess their perceptions on the joint EMA-HMA statement and downstream implications to biosimilar utilization policies.

RESULTS & DISCUSSION

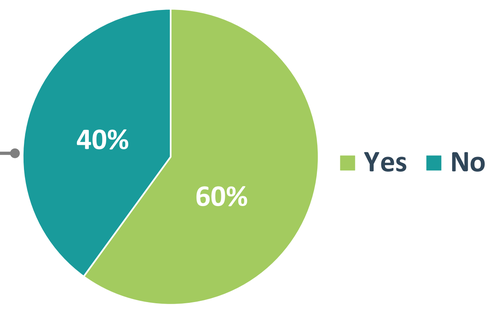
Payers' Awareness and Level of Support of EMA-HMA Biosimilar Endorsement

Most payers interviewed (6/10) were aware of the recent EMA-HMA statement on the scientific rationale supporting the interchangeability of biosimilars. Yet regardless of their awareness, payers are highly supportive of the EMA endorsement as they consider the potential increase of cost-savings from biosimilar utilization. They are hopeful the EMA positioning will help relieve any remaining physicians, patients, and other stakeholder's concerns associated with the safety and/or efficacy of these lower-cost options on top of local HTA bodies' endorsements of biosimilars.

7/7
Payers highly support EMA-HMA endorsement

Payer Awareness of the EMA-HMA Biosimilar Endorsement (N=10)

GBR	N=1/2
ITA	N=1/2
DEU	N=1/2
FRA	N=1/2



Potential Impact of EMA-HMA Endorsement on Biosimilar Policy Changes

- Overall, payers expect biosimilar prescribing practices not to majorly change in the future. For instance, they do not anticipate INN prescribing to become mandatory for biologics even if it could facilitate biosimilar interchangeability. Likewise, most payers do not foresee EMA endorsement to impact INN prescribing practices, apart from ESP payers who view it as an additional driver for hospital managers and pharmacy directors to endorse the use of the cheaper biologic. EU4 payers foresee continuing to encourage this practice, noting that competitive tenders and rebate contracts (DEU) already guide physicians to choose the most profitable treatment option. Thus, they do not deem necessary an INN prescribing mandate. Simultaneously, UK payers insist on physicians prescribing by brand name to ensure the most cost-effective options are used and facilitate access to the original biologic in situations of medical need, avoiding patient confusion and pushback (note: this option is reserved for treatment-experienced patients across markets, in case a biosimilar is contracted).
- Likewise, payers estimate the likelihood of mandatory biosimilars prescribing to treatment-naïve patients to be low despite regarding it as a key vehicle to biosimilars' uptake. Most payers do not consider this enforcement required because they view it as being largely embedded in physicians' current treatment practices. They are noticing healthcare providers initiate therapy of biologic-naïve patients with the cheapest/contracted biologic (subject to potential sanctions in some markets). Subsequently, payers expect a limited impact of EMA endorsement in physicians' practice. A few payers (ITA, FRA) nonetheless, hope the EMA endorsement can help increase acceptance of biosimilar prescribing among the few physicians who are still reluctant to adopt these options.
- EU4 + UK payers are generally content with the high biosimilar prescribing quotas and biosimilar uptake in their countries, partially attributing them to biosimilar switching despite being allowed only upon physician's consent and/or in the hospital settings in most cases. Therefore, they believe there is a low probability of change in the level of prescribing quotas and biosimilar switching. Nevertheless, FRA and DEU payers perceive biosimilar interchangeability can further increase in their markets, particularly with EMA endorsement influencing physicians not currently permitting switching. N=3 payers (DEU, FRA, ESP) underline this switching practice could become more established if pharmacists were given an economic incentive.
- Payers hold polarized views on automatic substitution. For instance, UK payers consider automatic substitution to be against NICE values and do not foresee it being applied, especially with the high biosimilar quotas they observe. Similarly, ITA payers esteem automatic substitution to be challenging to implement at the national level, in spite of a few regional hospital pharmacies already implementing it with biosimilars that have been longer in the market (e.g., erythropoietin); they suppose EMA endorsement could encourage other regions to follow (although with probably marginal impact). ESP payers view automatic substitution as feasible at the hospital level, especially with EMA endorsement. Even on a greater scale, DEU is already trying to introduce laws for biosimilar automatic substitution and FRA to broaden it for more molecules (beyond (peg)filgrastim). Hence, DEU payers, who have experienced political resistance and pushback to date, hope for a significant impact of the EMA endorsement in driving this change, whereas FRA payers expect a moderate impact.

Stakeholder Receptivity towards biosimilar policies

- Overall, payers are receptive to changes in biosimilar policies because of the anticipated cost-savings, whereas physicians seem to be moderately conservative due to their brand loyalty, at the eyes of payers.

	Overall Potential of Change	Level of impact of EMA endorsement	Supporting Quotes
Mandatory INN prescribing	Low: GBR, FRA, ITA, DEU, ESP: High	Low: GBR, FRA, ITA, DEU, ESP: High	"This would remain open on the decision of the prescriber even with EMA endorsement." - Ex-Payer (FRA)
Mandatory prescribing of BSM to biologic-naive patients	Low: ESP, GBR, DEU, ITA, FRA: High	Low: ESP, GBR, DEU, ITA, FRA: High	"I cannot imagine any mandatory statement from AIEA regarding this policy." - Ex-Payer (ITA)
Increase biosimilar prescribing quotas	Low: GBR, DEU, ESP, ITA, FRA: High	Low: GBR, FRA, DEU, ESP, ITA: High	"I think this will increase as we expect a biosimilar to provide 50-60% in savings." - Ex-Payer (GBR)
Automatic substitution at the pharmacy level	Low: GBR, ITA, ESP, DEU, FRA: High	Low: GBR, ITA, FRA, DEU, ESP: High	"If EMA and other systems allow it, we will have pressure." - Ex-Payer (DEU)
Interchangeability/ switching policies	Low: ITA, GBR, ESP, FRA, DEU: High	Low: ITA, GBR, ESP, FRA, DEU: High	"This is already happening. Today you get drug A, tomorrow drug B." - Ex-Payer (ESP)

CONCLUSION AND LIMITATIONS

Conclusion

Biosimilar uptake is increasing in the EU4 + UK markets driven by the joint effort of local bodies and payers in incentivizing physicians for their broader use. Payers note although most physicians feel comfortable utilizing biosimilars, some specialists such as rheumatologists and neurologists are still concerned about their long-term efficacy / safety and prefer to remain loyal to branded products. It seems that guidance from the local governments / HTA bodies has the most impact on payers' and physicians' practices, nevertheless, the EMA endorsement could help expedite biosimilar integration and incorporation into European markets. Future regulatory and legislative changes both on a national and EMA level can significantly stimulate biosimilar interchangeability at the hospital and pharmacy levels.

Limitations

This research was conducted in October 2023 and is based on a small sample size of N=10 payers from select markets and secondary research dating between 2019 and 2023. Research including a larger sample with additional European markets may need to be conducted to further validate these findings and should only be considered directional.

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ACRONYMS: AE: Adverse Event; BSM: Biosimilar; CCG: Clinical Commissioning Groups; EMA: European Medicines Agency; EU: Europe; HCP: Healthcare Provider; HMA: Heads of Medicines' Agencies; HTA: Health Technology Assessment; INN: International Nonproprietary Names; MHRA: Medicines and Healthcare Products Regulatory Agency; Rx: Prescription; UK: United Kingdom