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BIOSIMILAR ASSESSMENT FRAMEWORKS & POLICY SHIFTS IN THE EU IN THE POST-COVID CONTEXT

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INTRODUCTION & OBJECTIVES

Recent years have witnessed EU markets updating their biosimilar policies; however, there remain countries where the full cost-savings potential of biosimilars is yet to be realized. This research aims to review the current EU biosimilar landscape, and to investigate the most recent policy shifts as an indicator of expected evolution in the post-COVID environment, as payers express growing interest in healthcare savings.

METHODOLOGY

A qualitative assessment of current EU biosimilar policy was performed, focusing on N=7 markets (DEU, FRA, ESP, ITA, GBR, DNK & ROU) and investigating N=4 key metrics (market access / HTA processes, pricing rules, pharmacy substitution and prescriber incentives). This was followed by an investigation into emerging global policy shifts and findings were used to identify trends and predict the expected changes in the post-COVID context.

BACKGROUND

Almost 20 years ago, the EMA led the world in establishing a regulatory pathway for biosimilars to enter the market and compete with reference biologics [See Figure 1]. This was followed by the first ever EMA biosimilar approval of OMNITROPE (somatropin) in 2006, while the FDA trailed behind with no biosimilar products approved until in 2015, almost a decade later. Today, the EMA has >80 biosimilars approved; and while the current adoption and level of biosimilar policy is increased compared to the USA, there are still significant access and uptake hurdles.

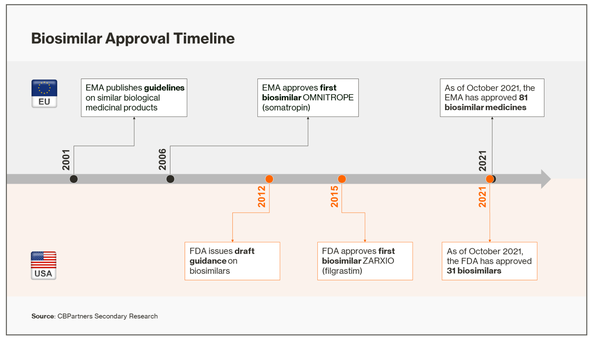

FIGURE 1: BIOSIMILAR APPROVAL TIMELINE

CONCLUSIONS

In the EU market, a broad array of policies and initiatives have been employed to encourage biosimilar use, tackling uptake through novel pricing mechanisms and incentives at the prescriber level. While some markets lag behind in terms of progress, they are likely to start to borrow those mechanisms which have shown success in neighbouring markets. Further, as more and more biologics exit their period of exclusivity and additional healthcare savings are sought in the post-COVID environment, it is expected that novel biosimilar initiatives will emerge across markets, including the steps towards expedited access and reimbursement pathways and automatic pharmacy substitution which have already initiated.

ABBREVIATIONS

AIFA: Italian Medicines Agency; AMNOG: German Pharmaceuticals Market Reorganisation Act; CCG: Clinical Commissioning Group; CEPS: French Pricing Committee; EMA: European Medicines Agency; FDA: Food and Drug Administration; HTA: Health Technology Assessment; MHRA: Medicines and Healthcare Products Regulatory Agency; MoH: Ministry of Health; MNF: Manufacturer

RESULTS

CURRENT LANDSCAPE (PRICING RULES & PRESCRIBER INCENTIVES)

Across the EU, markets currently leverage a variety of approaches to drive down prices upon biosimilar entry. Mandatory discounts is one of the more widely implemented mechanisms but does not actually appear to correlate to the lowest net prices or greatest uptake, given that price erosion tends to stagnate at the level of initial cuts [See Figures 2 & 3]. Instead, approaches showing greater success include free pricing within the confines of reference price groups which is seen in both DEU and ESP and results in sustainable downwards pricing pressure as reference prices are cyclically re-evaluated. Similarly, in GBR, there is no mandatory discount for biosimilars, but net discounts often reach >50%, due to effective tendering at the CCG level.

However, tendering systems can show variable efficacy across markets. For example, in ROU, single-winner tenders are implemented at the hospital level but these tenders are not always reopened upon biosimilar entry and originator manufacturers have been known to employ anticompetitive tactics by issuing tenders just prior to biosimilar entry to delay competition until the next round of tendering. There is also a lack of a predictable set of tender rules in ROU, resulting in low manufacturer participation. By contrast, the single-winner tendering system employed in DNK has shown much greater success given that it is implemented at the nation-wide level and manufacturers winning a tender are ensured to gain the entire market volume. This winner-takes-all approach results in rapid and broad uptake for the biosimilar given that hospitals and pharmacies will no longer stock the originator. Multi-winner approaches can also show a similar degree of success if clearly structured. For example, the multi-winner tender for adalimumab in GBR assigned biosimilar manufacturer contracts in different regions with more market share awarded to those priced most competitively.

In addition to tendering, GBR additionally promoted adalimumab biosimilar uptake at the prescriber-level through use of a nationally set reference price for reimbursement, creating provider incentive to prescribe the lowest cost biologic. This is similar to the gainsharing system in place for hospital products in FRA, where any savings generated through hospital negotiation are shared between the prescriber and CEPS to incentivize seeking the lowest price possible. An alternate and effective mechanism to promote uptake at the prescriber level is that of regional biosimilar quotas. A strong example is seen in DEU where contracts are implemented between regional physician associations, sickness funds and providers with set thresholds for biosimilar prescription (e.g., 2018 contract with the Techniker Krankenkasse sickness fund, outlining a 60% target for etanercept, and 80% for infliximab and rituximab). Conversely, such quotas appear less well spread in markets such as ITA and ESP, resulting in a more variable level of uptake across the country. Further, AIFA's biosimilar position paper aims to promote biosimilar favorability amongst prescribers, but has proved low impact given that it is not tied to concrete financial incentives.

These findings highlight the broad array of mechanisms which have been employed to tackle biosimilar pricing and prescriber incentives in the EU, and call attention to the markets which could borrow policies from their neighbour states to advance progress further. However, we also expect additional innovative approaches to emerge.

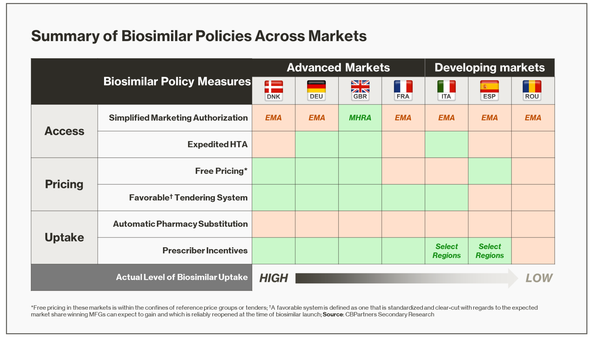

FIGURE 2: SUMMARY OF BIOSIMILAR POLICIES ACROSS MARKETS

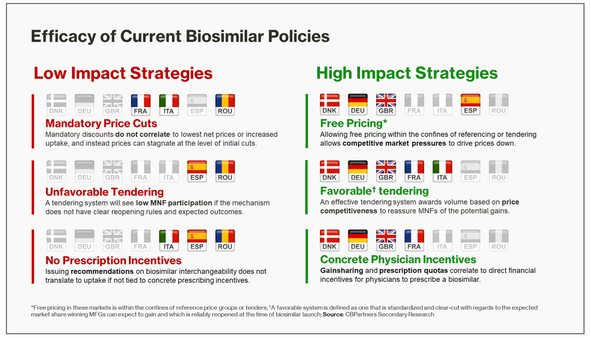

FIGURE 3: EFFICACY OF CURRENT BIOSIMILAR POLICIES

FUTURE OUTLOOK (ACCESS / HTA PROCESSES & PHARMACY SUBSTITUTION)

The economic pressures of the COVID-19 pandemic highlighted the financial fragility of the healthcare systems, built up over decades due to rising patient demand and increased spending on biologics. While EU payers have been looking to biosimilars as a cost-saving mechanism for over a decade now, this is only likely to increase further in the post-COVID context. As such, markets will be looking for new opportunities to eliminate barriers to biosimilar uptake.

ITA and GBR have most recently developed tailored access and reimbursement pathways for biosimilars as a mechanism to accelerate and increase uptake [See Figure 4]. In December 2020, AIFA introduced a new streamlined procedure for pricing and reimbursement of biosimilar drugs which considerably simplifies the process, reducing involvement of AIFA's scientific and pricing committees when biosimilar manufacturers submit a price in compliance with mandatory discounts. This is comparable to the process seen in DEU in which biosimilars are exempt from undergoing AMNOG benefit assessment. In GBR, exit from the EU was taken as an opportunity to go one step further and update the entire marketing authorization process for biosimilars. According to finalized guidance published by the MHRA in May 2021, the new pathway significantly reduces the level of evidence required for biosimilars to achieve market access, omitting the requirement for comparative efficacy data or in vivo studies in animals. It is likely that we will see such tactics correlate to accelerated time to market for biosimilars following loss of exclusivity, as well as increased biosimilar competition as manufacturer evidence requirements are lowered.

Future Outlook

	Tailored Access & Reimbursement Pathways		Automatic Pharmacy Substitution	
Markets Leading the Trend	ITA	GBR	DEU	ESP
Timelines	**December 2020**	**May 2021**	**Expected 2022**	**Uncertain**
Structure	**Reduced involvement** of scientific and pricing committees in access	Eliminated requirement of **comparative efficacy data** for approval	Legal framework for automatic substitution on a **case-by-case basis**	Mandatory dispensation of the **less costly drug** at the pharmacy

Source: CBPartners Secondary Research

FIGURE 4: FUTURE OUTLOOK

However, markets will also need to increase biosimilar uptake at the provider-level. One mechanism which has been employed for generics is automatic substitution at the pharmacy, allowing pharmacists to switch from originator to generic without intervention of the prescriber or patient [See Figure 4]. At present, this has not been practiced for biosimilars in EU5 markets, but certain policy shifts suggest this may change in the future. In DEU, the German Health Ministry laid out proposals back in 2018 for a new legal framework which is expected to launch in 2022 and which would allow automatic pharmacy substitution of specific biosimilars on a case-by-case basis. Similarly, in ESP, an action plan on the use of biosimilars published by the MoH in 2019 outlined intention to mandate pharmacists to dispense the less costly drug. This would not only result in automatic substitution when necessary but also potentially foster competition amongst manufacturers and lead to lower prices, although the timelines for implementation remain unclear. Looking further afield, an enforced physician switching policy is due to launch in CAN in 2022, further supporting that an increased focus and acceptance of mandatory switching at both the pharmacy and prescriber-level may be seen globally in the future.

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