Biosimilar medicines Uptake

factsheet

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Problem Statement

The sustainability of healthcare systems is a challenge for many European governments. Multiple factors, such as a growing and ageing population, increased disease burden, the introduction and the high cost of new innovative medicines, have put **pressure on healthcare** budgets across Europe. Biologic medicines take an important part of the pharmaceutical budget and a growing number of new pharmaceutical therapies are biological molecules. Biosimilar medicines have offered patients increased access to these life-altering biologic therapies. 15 years after the first biosimilar approval in Europe, we have reached more than 2 billion patient treatment days of safe clinical experience, accompanied by a growing trust in these more affordable biologic medicines.

Over the next 10 years, many biological medicines are set to lose market exclusivity. This represents an opportunity for the market to harness more competition in the biologic medicines market and offer invaluable opportunities for healthcare systems to **improve patient access, improve healthcare budget sustainability and significantly reduce equity gaps** across Europe. The reduction of treatment costs with biosimilar medicines frees up resources which can then be **reinvested** into better care for patients and sometimes make previously unaffordable innovative therapies, more affordable.

Policy recommendations

- Implement **thoughtful biosimilar medicine policies** that balance the benefits of competition, biosimilar use to increase patient access where necessary, and increase the affordability of treatments allowing reinvestments in health care.
- Design a **biosimilar policy framework** capable of delivering value for all stakeholders, building on the vast European experience. The **core components** of such framework are outlined here:
  - Political vision, will, action and targets towards healthier communities.
  - Involvement of all relevant stakeholders to build trust.
  - Implementation roadmaps allowing time for tangible results.
  - A coordinated and holistic design with multiple comprehensive policies.
  - A biologic market driven by level-playing field competition.
  - Resilience and continuous improvement reflecting contextual changes.
- Strengthen **shared decision making** and the **physician-patient relationship** has a central role throughout the course of biologic treatment (therapy selection, patient information/education and clinical oversight over time).

POLICY AREA	SUSTAINABILITY MEASURE	SUSTAINABLE MARKET STATUS
Regulatory environment and clinical guidelines	Time from EMA approval to first biosimilars sales	Instant or very short market entry after approval
	Treatment guidelines for biosimilar use	Publication of multiple guidelines on usage and protocols prior to first biosimilar entry
	Physician switching policies	Authorisation and guidance of physician-led ability to switch to a biosimilar medicine at entry of first biosimilar on the market
	No biologic pharmacy substitution	No biologic pharmacy substitution allowed
Awareness and education	Comprehensive training / education for patient	Access to comprehensive and unbiased training or education prior to first biosimilar entry
	Comprehensive training / education for physician	
Incentives	Patient incentives to promote biosimilar use	Incentives in place to encourage use of most economically advantageous product upon introduction of competition
	Prescription quotas or financial incentives for providers that do not restrict physician choice	An incentive or quota that does not restrict physician choice
Pricing rules and dynamics	Originator price not subject to mandatory price cuts	No forced originator price cuts by central authorities required, market forces to determine price
	Molecule pricing not subject to reference price	No reference price determined by central authorities, market forces to determine price
Purchasing mechanisms	Length of contracts	12- to 24-month contracts ensure market competitiveness and avoid patients are switched often
	Tender timing relative to biosimilar availability	Tender opens upon introduction of competition
	Time from tender award to delivery	4-6 months lead time to allow necessary preparations and stock build-up
	Number of winners	Consistently award multi-winner tenders to allow of market sustainability
	Winner decision criteria beyond price	Decision based on the most economically advantageous tender offers (e.g. incorporating sustainability, price,

Sustainability examples

- In **Denmark**, Amgros (secures the supply of drugs to public hospitals) divided the country into two different regions when procuring Adalimumab after biosimilar market entry. This allowed two competitors to supply the market, reducing market reliance on a single manufacturer while maintaining fast biosimilar medicines uptake, helping to ensure long-term competition and supply reliability for patients.

- In **France**, authorities set a national target for biosimilar use and created opportunities to implement policies to increase biosimilar prescription. France's objective is to achieve 80% biosimilar market penetration by 2022. In addition, France started piloting policy measures to increase biosimilar penetration in October 2018. While the project is scheduled to run for 3 years, policymakers are already looking to preliminary results based on defined KPIs and assessing and implementing alternative measures (e.g. incentives targeting hospital purchasing and for outpatient prescribers) to reach the target biosimilar penetration.

Relevant documentation

- IQVIA Biosimilar Scorecard 2020
- Positioning Statements on Physician-led Switching for Biosimilar Medicines
- Biosimilar medicines Group (Medicines for Europe) Position on biologic pharmacy substitution