PATIENTS
Improved access to medicines

PHYSICIANS
Opportunities to treat more patients with appropriate therapies

PAYERS
Cost savings and financial sustainability of healthcare systems

INDUSTRY
Reasonable return on investment with the continued attractiveness of R&D investment in new medicines development

Education and Understanding + **Experience and Use** + **Sustainable Pricing** + **Rational Decision Making** = **Clinical, Economic, & Patient Benefits**

1 EDUCATION & UNDERSTANDING

Multi-stakeholder understanding and acceptance of biosimilar medicines is critical for supporting long-term sustainability.

- Clear, non-promotional and unbiased information
- Focused on science
- Easily accessible & pro-actively communicated

2 EXPERIENCE AND USE

Accelerated experience and uptake of biosimilar medicines to establish confidence and trust is important for the short term benefit and long term sustainability of both biosimilar medicines markets and healthcare systems.

- Incentives & clinical guidelines
- Real World Evidence
- Multi-stakeholder approach

3 SUSTAINABLE PRICING

Avoid pricing policies that hinder competition and artificially force/mandate downward pricing which undermines the sustainability of markets.

- Tailored approach
- Encourage competition
- Incentivise R&D

4 RATIONAL DECISION MAKING

Pricing, procurement, positioning, and utilisation decision-making processes should be transparent and should not delay access to biosimilar medicines.

- Fair market
- More than only price
- Clinician involvement

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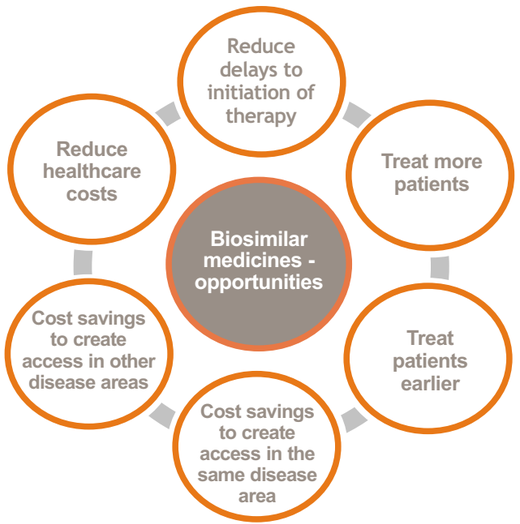
Full report available on www.medicinesforeurope.com

biosimilar medicines
better access. better health.

GfK

The EGA has become Medicines for Europe

Factors Supporting a Sustainable European Biosimilar Medicines Market



BIOSIMILARS MARKET MUST REMAIN SUSTAINABLE FOR ALL STAKEHOLDERS TO BENEFIT FROM THE OPPORTUNITIES

CONDITION: to be attractive and deliver continuous benefits to four key stakeholder groups in both the short and long term

1 EDUCATION & UNDERSTANDING

Clear, non-promotional and unbiased information

Regulators (e.g. EMA, European Commission, National Competent Authorities) and other stakeholders should provide clear, unbiased and non-promotional information to doctors, other healthcare professionals, payers and patients.

Focused on science

Education is required on the scientific concept of biosimilar medicines, their quality, safety and efficacy and the EMA approval process. In addition, the concept of “indication extrapolation”, an essential aspect of the biosimilar medicines regulatory pathway, should be clearly communicated and explained to all stakeholders in a context and language that provides complete understanding and support.

Easily accessible & pro-actively communicated

Physicians should be made aware of the easy access to unbiased and available information on biosimilar medicines (e.g. EMA Q&A on biosimilar medicines for the general public, the EMA European Public Assessment Reports (EPARs) or the EC Consensus Information document).

2 EXPERIENCE AND USE

Incentives & clinical guidelines

Policies should incentivise the early use of biosimilar medicines. Clinical guidelines are valuable to accelerate the uptake of biosimilar medicines. Procurement and utilisation should be transparent and multifaceted, not driven by the consideration of cost alone.

Real World Evidence

The confidence and trust of physicians (and other stakeholders) should be reinforced by supporting and incentivising appropriate early use, and encouraging them to collect and publish Real World Evidence (RWE).

Multi-stakeholder approach

Utilisation and procurement policies should evolve to include multi-stakeholder input and agreement.

3 SUSTAINABLE PRICING

Tailored approach

Biologic medicines are very complex to develop and manufacture. It is estimated that developing a biosimilar medicine takes 8 to 10 years and costs between €90 million and €180 million. In addition, post-marketing requirements are very costly.

Encourage competition

Maintaining and encouraging competition is the best way to ensure that all stakeholders receive the most value. Regulation between biosimilar medicines should create a level playing field for competition.

Incentivise R&D

Avoid pricing and procurement policies that drive prices to levels that threaten the financial viability of the biosimilar medicines industry and undermine continued investment by the pharmaceutical industry in future innovation (R&D). Thoughtful biosimilar medicines pricing will incentivise manufacturers to continue investing in new biosimilar medicines, thereby giving healthcare systems sustained savings and allowing more patient access to the best possible therapy options.

4 RATIONAL DECISION MAKING

Fair market

Procurement decision-making should not distort the market or lead to an arguably unfair position of dominance (e.g. originator long-term contracts/tenders prior to biosimilar approval). The timing and type of tenders must be aligned with the opportunity to deliver benefits to all stakeholders.

More than only price

Decision criteria should look at cost in the context of additional factors (e.g. outcomes and service provision) and balance procurement decisions to reflect factors other than price.

Clinician involvement

Procurement decision-making should include input from the clinical community and, particularly in the early phases, should provide clinicians with prescribing choice. Without general support from the clinical community any tender decision may be difficult or impossible to uphold.