



## **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



Experience and Use

Sustainable Pricing

Rational Decision Making

Clinical Economic. & **Patient Benefits** 

**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

**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 quidelines

Real World Evidence

SUSTAINABLE PRICING

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

Tailored approach Encourage competition

**RATIONAL DECISION MAKING** 

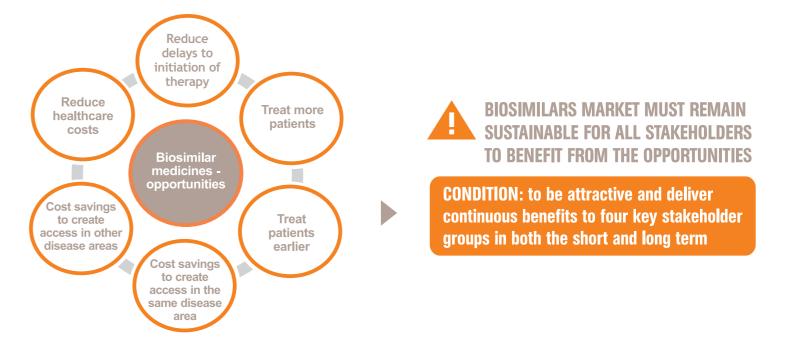
Pricing, procurement, positioning, and utilisation decision-making processes should be transparent and should not delay access to biosimilar medicines.

More than only price



The EGA has become Medicines for Europe

# **Factors Supporting a Sustainable European Biosimilar Medicines Market**



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 involvemen

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.