



EuropaBio launches recommendations to enhance transparency of biosimilar labels

PRESS RELEASE

6 June 2017, Brussels – EuropaBio has developed recommendations for changes to the Summary of Product Characteristics (SmPC) of biosimilars that would result in an enhanced level of transparency in the label.

EuropaBio members believe that the current EU approach to labelling does not reflect the specificities of biosimilars and that the SmPC of a biosimilar product should contain additional information to facilitate greater transparency for physicians and patients.

Based on interactions that EuropaBio had with various stakeholders including physicians and patients over recent years, we have concluded that label transparency would be enhanced by implementing the following small yet meaningful changes to the biosimilar SmPC:

1. Adding a statement with the definition of biosimilarity
2. Adding a direct link to the EPAR next to the biosimilarity statement
3. Moving the biosimilarity statement to the top of the SmPC

“The EMA and the European Commission are going to great lengths to increase physicians’ and patients’ understanding of biosimilars”, said Ronald Jager, EuropaBio Healthcare Biotech Director, “We are convinced that a more transparent labelling approach would contribute to further facilitate the understanding and acceptance of biosimilars.”

EuropaBio’s recommendations on the SmPC of biosimilar products do provide a basis for future exchanges and next steps on this area with regulators and other stakeholders.

ENDS

Background – EuropaBio resources and activities on biosimilar labelling

- Results from the first ever European biosimilars labelling survey (2016) – [link](#)
- EuropaBio – EBE workshop on ‘Biosimilars labelling’ (2016) – [link \(GaBI Journal report\)](#)
- EuropaBio Statement on Labelling of Biosimilars (2014) – [link](#)
- EuropaBio Position Paper on Biosimilars in Europe (2014) – [link](#)

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About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents 79 corporate and associate members and bio-regions, and 17 national biotechnology associations in turn representing over 1800 biotech SMEs.

Read more about our work at www.europabio.org.

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