European stakeholder learnings regarding biosimilars: Part I – improving biosimilar understanding and adoption

BioDrugs

Liese Barbier[1*], Steven Simoens[1], Arnold G. Vulto[1,2+*], Isabelle Huys[1+]

[1]KU Leuven, Department of Pharmaceutical and Pharmacological Sciences, Leuven, Belgium
[2]Hospital Pharmacy, Erasmus University Medical Center, Rotterdam, the Netherlands

[+] Joint last author: these authors contributed equally to this work

[*] Corresponding author:

Arnold G. Vulto Contact: a.vulto@gmail.com

Liese Barbier Contact: liese.barbier@kuleuven.be

Online Resource 3. Main topics addressed during the interviews

Main topics addressed during the interviews
1. Views about stakeholder information and education needs for biosimilars
2. Views about aspects related to regulatory evaluation of biosimilars
Questions about the general framework
Questions about the tailoring of phase III clinical data
Questions about extrapolation of indications
Interchangeability designation
Immunogenicity testing
Small differences existed between the topic guides of the different stakeholder groups, allowing tailoring of the questions to the individual stakeholder group