THE ROLE OF REGULATORY GUIDANCE AND INFORMATION DISSEMINATION FOR BIOSIMILAR MEDICINES – THE PERSPECTIVE OF HEALTHCARE PROFESSIONALS AND INDUSTRY

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BACKGROUND & OBJECTIVE

Background: a lack of knowledge among stakeholders about biosimilars and their regulatory framework may act as barrier for the use of biosimilars.

Objective: this study aims to (i) map regulatory guidance and information dissemination for biosimilars by the European Medicines Agency (EMA) and the National Competent Authorities (NCAs) in Europe and (ii) investigate the perspectives of healthcare professionals (HCPs) and industry about regulatory information for biosimilars.

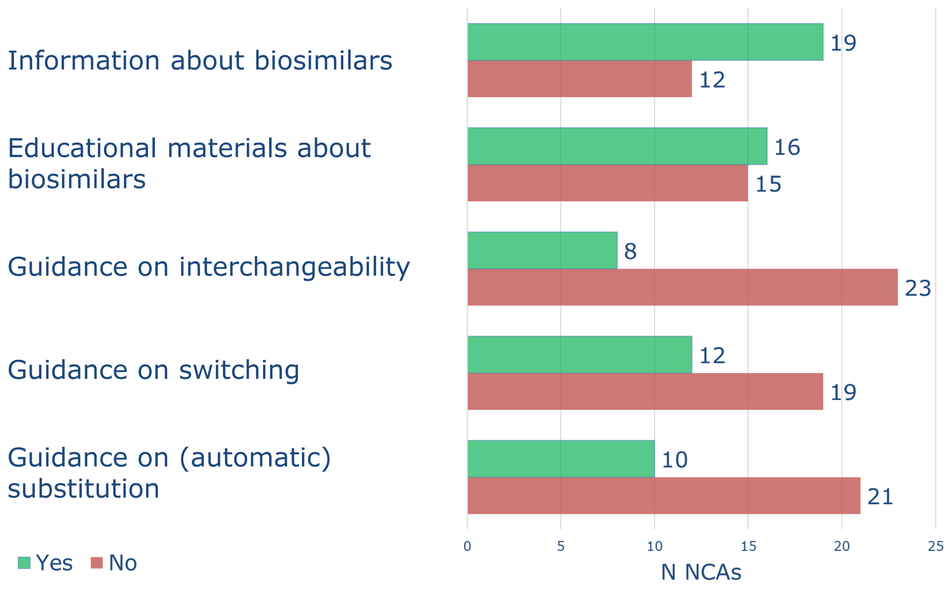
METHODS

The study consisted of a (i) narrative review of the literature, (ii) screening of the EMA and NCA websites in Europe (EU Member States (MS) + European Economic Area (EEA) countries) and (iii) semi-structured interviews with HCPs and industry across EU MS. Interviews were audio-recorded and transcribed *ad verbatim*. Transcripts were analysed via the thematic framework approach.

RESULTS

MAPPING OF NCA REGULATORY GUIDANCE AND INFORMATION DISSEMINATION FOR BIOSIMILARS

Guidance on biosimilars published on NCA websites (N=31)



Automatic substitution for biosimilars in Europe

Allowed (under specific conditions)	Not allowed		(Planned) changes to legislation	No info
France[2]	Austria	Italy	Germany[1]	Bulgaria
Hungary[2]	Belgium	Malta	Norway[4]	Cyprus
Latvia	Croatia	Netherlands[3]		Estonia
Lithuania	Czech Republic	Portugal		Liechtenstein
Poland[5]	Denmark	Romania		Luxembourg
	Finland	Spain		Slovakia
	Greece	Sweden		Slovenia
	Iceland	UK		
	Ireland			

1. New legislation planned (GSAV), that will allow biologicals to be substituted at pharmacy level
2. Authorized by law under specific conditions (e.g. only for treatment naïve patients), but not implemented in practice
3. For insulin biosimilars, insurance companies are increasingly forcing pharmacies to substitute to the biosimilar
4. Proposal to alter Pharmacy Act § 6-6 (basis for generic (automatic) substitution in pharmacies), eventually permitting automatic substitution of new classes of medicinal products, e.g. biological drugs
5. Automatic substitution is not recommended, but due to a lack of regulation or specific guidance, automatic substitution may occur

STAKEHOLDER PERSPECTIVES ABOUT THE ROLE OF REGULATORY GUIDANCE AND INFORMATION FOR BIOSIMILARS

- N semi-structured interviews = 14 (7 HCPs/7 industry representatives)
- HCPs and industry identified that both EMA and NCAs play a crucial role in informing and guiding stakeholders about (the development/evaluation/use of) biosimilars
- EMA was considered a primary information source by most interviewees, acknowledging the comprehensive and trustworthy nature of the information and guidance provided
- Opinions about the transparency and insight provided in the evaluation of biosimilars by the EPAR varied
- On a national level, a need for more guidance by NCAs, specifically regarding interchangeability, (multiple) switching and substitution, was identified. This gap seems to be partially compensated by information from HCP associations

CONCLUSION

Whereas stakeholders recognize the role of EMA in guiding and informing them about biosimilars, room for improvement about the guidance by NCAs about the use of biosimilars in clinical practice was identified. The need for further actions by NCAs was underlined by the lack or limited level of information about biosimilars on various NCA websites. In addition to the role of regulatory bodies, stakeholders recognized that peer-to-peer information can help consolidating confidence about biosimilars.

ABBREVIATIONS

EEA: European Economic Area, EMA: European Medicines Agency, EPAR: European Public Assessment Report, EU: European Union, GSAV: Gesetz für mehr Sicherheit in der Arzneimittelversor-gung, HCPs: healthcare professionals, MS: member states, N: number, NCAs: National Competent Authorities

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https://pharm.kuleuven.be/clinpharmacotherapy/mabel