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Autore	Osmane Malik
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Nota di contenuto	Rift-lines within european regulatory framework for biosimilars when taking heterogeneity and variation during lifecycle of the reference biologic and the biosimilar into account; Abstract; Table of Contents; Acknowledgements; List of abbreviations; Chapter 1.0: Introduction; 1.0. Rationale on the selection of the topic (as guide for future students); 1.1 Definitions; 1.2 Statement of the main problem, subsequent research questions and test-functions; 1.3 Study "Within Scope" and "Out of Scope"; 1.4 Description of the European Regulatory Environment with Regard to Biosimilars 1.5. Why are biosimilars interesting for the generic industry?Chapter 2.0: Literature review; 2.1. Re-presenting the current biosimilar legislation and regulatory requirements; 2.2 Life cycle in relation to heterogeneity and variation; 2.3 Screening the above presented literature related to current biosimilar regulation withregard to the research questions; 2.4. Reference to other biosimilar regulations; 2.2 Teil 2:Life cycle in relation to heterogeneity and variation 2.3 Teil 2: Screening the above presented literature related to current biosimilar regulation with regard to the research questions2.4. Teil 2: Reference to other biosimilar regulations (for informationalpurposes only); Chapter 3.0: Materials and Methods; 3.1 Methods used and

rational for choosing them; 3.2 Rationale for using the employed research methodologies; 3.3 Practical aspects; Chapter 4.0: What are the implications of heterogeneity and variation through the life cycle of the biosimilar and the reference biologic, from a European perspective?; 4.1 Introduction
4.2 Experimental procedure (methods and materials) employed4.3 Results for main research questions 1.0 and directly associated research questions 1.1 and 1.2 that discuss the impact of the dynamic to the quality profile; 4.4 Discussion; Chapter 5.0: What should be the scope of trials?; 5.1 Introduction; 5.2 Experimental procedure (methods and materials) employed; 5.3 Results for the series 2 research questions; 5.4 Discussion; Chapter 6.0: Why is extrapolation of indications for biosimilar controversial?; 6.1 Introduction; 6.2 Experimental procedure (methods and materials) employed
6.3 Results from why is extrapolation of indications for biosimilar controversial?6.4 Discussion; Chapter 7.0 Integrated discussion; 7.1 Part I: General Comments; 7.2 Part II: Findings evaluation; 7.3 Part III: Discussion of solutions (and outlook); Chapter 8.0 Integrated conclusion; Bibliography or References; List of Appendices; Appendix: 1; Appendix: 2; Appendix: 3; Appendix: 4; Appendix: 5

Sommario/riassunto

Biopharmaceutical medicinal products (biologics) represent a huge financial market. Thus upon patent protection expiry of the innovator (reference) biologic there is interest from industry to gain a portion of this market by launching a 'similar' biologic at a reduced development cost, thus boosting potential gains. The EMA responded to this desire and lead the guidance process with industry on the topic of biosimilars. Based on the experience gained with biosimilars in the past, the EMA started to introduce a second generation series of guidance documents, which take into account the past, cu