
15 Biosimilars in the EU *Regulatory Guidelines*

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CONTENTS

15.1	Introduction	395
15.2	Regulatory Framework in the European Union.....	396
15.3	Notes for Guidance or Guidelines	398
15.3.1	Guideline on Similar Biological Products.....	398
15.3.2	Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Quality Issues	399
15.3.3	Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Nonclinical and Clinical Issues	400
15.3.3.1	Nonclinical Studies	401
15.3.3.2	Clinical Studies—Efficacy and Safety	401
15.3.3.3	Extrapolation of Indications.....	402
15.3.3.4	Pharmacovigilance.....	403
15.3.4	Product-Specific Guidance	403
15.4	The First Decade.....	404
15.5	Remaining Challenges.....	405
15.5.1	Interpretation of Differences and Extrapolation of Therapeutic Indications.....	405
15.5.2	Pharmacovigilance and Traceability	407
15.5.3	Interchangeability and Substitution	408
15.6	Concluding Remarks	409
	References.....	410

15.1 INTRODUCTION

The clinical use of biologics (i.e., medicines obtained from biological material such as animal or human tissues or fluids, e.g., heparin or plasma-derived products or from microorganisms, e.g., some vaccines) and, particularly, biotechnological medicines (obtained using genetic engineering techniques) has been increasing in the last three decades. Insulin from animal origin for the treatment of diabetic patients was already widely used in 1923 (Teuscher, 2007). Its complete amino acid sequence was obtained in 1955; it was the first protein produced through a biotechnology