1. Record Nr. UNINA9910168748003321 Autore Kaeding Michael **Titolo** Pharmacovigilance in the European Union [[electronic resource]]: Practical Implementation across Member States / / by Michael Kaeding, Julia Schmälter, Christoph Klika Wiesbaden:,: Springer Fachmedien Wiesbaden:,: Imprint: Springer,, Pubbl/distr/stampa 2017 3-658-17276-2 **ISBN** Edizione [1st ed. 2017.] 1 online resource (XIV, 124 p. 13 illus., 12 illus. in color.) Descrizione fisica Disciplina 320 Soggetti Comparative politics Political economy **European Union Pharmacy** Comparative Politics International Political Economy **European Union Politics** Drug Safety and Pharmacovigilance Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Nota di contenuto Intro -- Contents -- Abbreviations -- List of Tables, Figures and Boxes -- Preface -- 1 Introduction -- 1.1 Background and Terms of Reference -- 1.2 Methodology: Selection of Countries -- 1.3 Methodology: Research Strategy -- 1.4 Summary of Evidence -- 1.5 Implementation Assessment Structure -- References -- 2 Pharmacovigilance -- 2.1 Fundamentals of Pharmacovigilance -- 2.2 Importance of Pharmacovigilance for Biologicals -- References -- 3 The EU Pharmacovigilance System -- 3.1 EU Institutions and Pharmacovigilance Actors -- 3.2 Legislative Developments -- 3.3 The Pharmacovigilance Reform: Directive 2010/84/EU and Article 102 -- References -- 4 Timely and Correct Transposition of Pharmacovigilance across Member States -- 4.1 Timely Transposition of Directive 2010/84/EU across Member States -- 4.2 Correct Transposition of Directive 2010/84/EU

across Member States -- 4.2.1 Correct Transposition - Processes and

Actors -- 4.2.2 Correct Transposition - Quality and Content -- References -- 5 Practical Implementation in Six Member States -- 5.1 ADR Reporting in the United Kingdom -- 5.1.1 The System -- 5.1.2 Perceived Challenges -- 5.1.3 Perceived Best Practices -- 5.2 ADR Reporting in Finland -- 5.2.1 The System -- 5.2.2 Perceived Challenges -- 5.2.3 Perceived Best Practices -- 5.3 ADR Reporting in Poland -- 5.3.1 The System -- 5.3.2 Perceived Challenges -- 5.3.3 Perceived Best Practices -- 5.4 ADR Reporting in France -- 5.4.1 The System -- 5.4.2 Perceived Challenges -- 5.4.3 Perceived Best Practices -- 5.5 ADR Reporting in Portugal -- 5.5.1 The System -- 5.5.2 Perceived Challenges -- 5.5.3 Perceived Best Practices -- 5.6 ADR Reporting in Germany -- 5.6.1 The System -- 5.6.2 Perceived Challenges -- 5.6.3 Perceived Best Practices -- References -- 6 Challenges and Best Practices in Perspective -- 6.1 Pharmacovigilance Systems -- 6.2 Major Challenges.

6.3 Comparison of Factors Contributing to Underreporting -- 6.3.1 Lack of Awareness -- 6.3.2 Complexity of ADR Reporting -- 6.3.3 Lack of Cooperation -- 6.3.4 Interconnectivity Problems -- References -- 7 Conclusions and Recommendations -- 7.1 Specific Recommendations in Relation to Article 102 -- 7.2 General Recommendations: National Healthcare Systems and Policy Options for Pharmacovigilance -- References.

Sommario/riassunto

This book is open access under a CC BY 4.0 license. The book presents the results of an in-depth comparative study assessing the implementation of the EU Pharmacovigilance Directive in six EU Member States. By going beyond legal transposition and instead focusing on practical implementation, this study aims to close a gap in EU compliance research. Based on qualitative interviews with relevant actors in Germany, Poland, Portugal, France, Finland and the UK, the authors identify perceived challenges and best-practices, issue recommendations, and thereby contribute to a better understanding of the factors that incentivize or impede the practical implementation of EU law at the national level. Content Introduction: Background and Methodology • Pharmacovigilance • The EU Pharmacovigilance System • Timely and Correct Transposition of Pharmacovigilance across Member States • Practical Implementation in Six Member States • Challenges and Best Practices in Perspective • Conclusions and Recommendations The authors Dr. Michael Kaeding is Professor for European Integration and European Union Politics at the Department of Political Science of the University of Duisburg-Essen, Germany and holds an ad personam Jean Monnet Chair in "Understanding EU Decision Making and Member States' Compliance with EU Policies". Julia Schmälter is a research assistant at the Jean Monnet Chair for European Integration and European Union Politics at the Department of Political Science at the University of Duisburg-Essen. Christoph Klika is a lecturer at the Department of Political Science at the University of Duisburg-Essen.