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## Preface

This implementation assessment, “Pharmacovigilance in the EU: Practical Implementation across Member States” is the result of intensive teamwork. The assessment was commissioned by AbbVie, directed by Dr Michael Kaeding and managed by Julia Schmälter. In addition, the group of collaborators included Christoph Klika, Roxana Dürsch, Annika Körner, Stella Malliara and Charline Ulrich.

“Pharmacovigilance in the EU: Practical Implementation across Member States” comes at a time when Europe faces rising populism and Euroscepticism, and a time when Europe needs to find effective responses to pressing European and global issues – in short, to develop a new narrative. Europe has to deliver by reaching out to its Member States and must prove more than ever its added value. Non-compliance with EU rules implies legal uncertainty and hampers the European regulatory framework in which citizens live and businesses operate. In addition, non-compliance frustrates further European integration, including the free movement of people, goods, services and capital, and potentially jeopardizes market competitiveness, social standards, national growth and employment performance across Europe.

Our implementation assessment studies the practical implementation of pharmacovigilance across Europe. European pharmacovigilance has been geared towards the detection of adverse reactions to medicinal products to ensure public health through product safety and to provide medicinal products with a high level of efficacy.

The research for this assessment would have been impossible without fruitful discussions and collaborations with colleagues and implementation scholars during the 10 months of investigation. Some of our thoughts that eventually turned into chapters were presented at conferences: the IRUN compliance workshop, “Non-compliance with EU Regulatory Norms, Rules and Values” at the University of Duisburg-Essen, the ECSA-C 11<sup>th</sup> Biennial Conference in Halifax, the ECPR Pan-European Conference on the European Union in Trento, the ECPR General Conference at the Charles University of Prague, and the GAfPA Patient Advocacy and Safety Conference in Brussels.

Furthermore, this assessment would have been impossible without the support of our interview partners. Many thanks to all those we met in Berlin, Bonn, Brussels, Helsinki, Lisbon, London, Liverpool, Paris, Reims and Warsaw, who contributed by kindly agreeing to give up their valuable time to participate in in-depth interviews conducted by the Duisburg-Essen pharmacovigilance research team. Moreover, the team is grateful to Monika Bähz and Peter Staniczek for their administrative support and to Elizabeth Meyer zu Heringdorf for her linguistic expertise.

Finally, the views expressed in this implementation assessment are those of its authors, and these views neither reflect those of their institution of employment nor its staff. The authors are solely responsible for any mistakes or inaccuracies.

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Brussels and Duisburg, December 2016

Pharmacovigilance in the European Union

Practical Implementation across Member States

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2017, XIV, 124 p. 13 illus., 12 illus. in color., Softcover

ISBN: 978-3-658-17275-6