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Sally Shorthose

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Legal Risks in EU Law Emilia Mišćenić, Aurélien Raccah, 2016-04-13 This book takes a completely new and innovative approach to analysing the development of EU law Within the framework of different important areas of EU law such as the internal market consumer protection law social law investment law environment law migration law legal translation and terminology it examines the Union s approach to the regulation and management of legal risks Over the years the Union has come to a point where it is becoming increasingly difficult to justify its authority to regulate in various areas of law In managing legal risks deriving from the diversity of Member States laws which create barriers to trade and hinder the Union s economy the Union itself has actually produced new legal risks that now have to be addressed This failure on the part of EU institutions to manage legal risks has contributed to legal uncertainty for actors operating on the internal market This book intends to contribute to the Union's smoother functioning and continuing development by proposing effective concrete solutions for managing the legal risks distorting the development of various areas of EU law It pursues an innovative and effective approach to identify legal risks their causes at the EU level and their impacts on the functioning of the Union and its Member States By presenting new approaches in this context the first book on legal risk management in the EU will actively promote the improvement of the EU lawmaking process and the application of EU law in practice **Guide to EU** Pharmaceutical Regulatory Law Sally Shorthose, 2017-02-17 In the European Union EU and its Member States as elsewhere the marketing of pharmaceuticals has become subject to an increasingly complex web of legislation and regulation resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but safe This useful volume lavs out this system with extraordinary clarity and logic Adopting a Europe wide perspective on the law governing pharmaceuticals expert authors from the law firm Bird stages and standards for creating a product dossier clinical trials how and when an abridged procedure can be used criteria for conditional marketing authorisations generic products and essential similarity paediatric use and the requisite additional trials biologicals and biosimilars homeopathic and herbal medicines reporting procedures pharmacovigilance parallel trade relevant competition law and intellectual property rights and advertising In addition national variation charts in many of the chapters illustrate eight major jurisdictions Belgium France Germany Italy The Netherlands Spain Sweden and the UK Sample forms and URLs for the most important Directives are included Pharmaceutical lawyers and regulatory advisers both in house and in private practice will welcome this unique book It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations

Guide to EU and UK Pharmaceutical Regulatory Law Sally Shorthose, 2023-01-10 In the European Union EU its Member States and the United Kingdom UK post Brexit as elsewhere the marketing of pharmaceuticals is subject to an ever more complex web of legislation and regulation resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but also safe This useful

volume lays out this system with extraordinary clarity and logic Adopting a Europe wide perspective on the law governing pharmaceuticals expert authors from the law firm Bird stages and standards for creating a product dossier obtaining a marketing authorisation how and when an abridged marketing authorisation procedure can be used criteria for conditional marketing authorisations generic products and essential similarity paediatric use and the requisite additional trials orphan medicinal products biologicals and biosimilars homeopathic herbal and similar medicines medical devices pandemics epidemics and vaccines pharmacovigilance parallel trade advertising and relevant competition law intellectual property rights and data protection regulation In addition sample forms and URLs for the most important reference materials are included Pharmaceutical lawyers and regulatory advisers both in house and in private practice will welcome this unique book It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations **Islamic Finance in Europe** Mohyedine Hajjar, 2019-05-10 Information about Islamic finance in European countries is usually provided by professional style reports offering practical data on implementation of standardized products However precise developments about material legal provisions applicable to contracts and their actual legal regime are not often detailed In order to fill this gap 15 researchers from across Europe contributed to this project They describe the state of actual Islamic finance in 10 European countries as well as applicable EU law By combining legal analysis with statistical description of existing practices and social demand this book provides an exhaustive account of the current potential of Islamic finance in Europe Common Legal Framework for Takeover Bids in Europe: Volume 2 Dirk Van Gerven, 2010-01-28 The Council Directive of 21 April 2004 on takeover bids sets forth the general principles applicable to takeover bids and clarifies certain minimum rules with respect to the procedure for a takeover bid the obligation to make a mandatory bid in the event a minimum threshold is crossed and the majority shareholder s squeeze out right as well as the minority shareholders sell out right Furthermore the Directive defines the authority which is competent to approve offer documents and supervise takeover bids and provides for optional restrictions on the actions of the target company s management and on defence mechanisms This book discusses the Takeover Directive and its implementing rules in each Member State of the European Union and the European Economic Area providing companies and their advisors with useful insight into the legal framework and principles applicable to takeover bids in the region $\mathbf{E}\mathbf{U}$ Sustainability Legislation and International Supply Chains Adolf Peter, 2025-10-17 This book provides an in depth analysis of the Corporate Sustainability Due Diligence Directive CSDDD including the European Commission's Omnibus Directive Proposal focusing on civil liability enforcement issues climate related transition plans and directors liabilities It also discusses other Environmental Social and Governance ESG sustainability related legislation and stock exchange rules in the EU the United States and China Using case studies involving multinationals such as BYD Shell RWE Borealis BMW VW and L Or all the book demonstrates the increasing negative impact of ESG related issues on a company s reputation and finances

Showing that international commercial arbitration is the ideal means for the resolution of ESG climate CSDDD related disputes between multiple parties the book compares the arbitration rules of 11 leading arbitration institutions in terms of consolidations and joinders It proposes an incentive mechanism for the contractual cascading of climate related targets and ESG related arbitration rules It also features more than 20 contractual template clauses aimed at i implementing the CSDDD throughout international supply chains ii reducing product service related GHG emissions including Scope 3 emissions year on year to achieve net zero across entire value chains and iii facilitating consolidations and joinders in ESG related multi party arbitrations. The book is directed at legal practitioners legislators of various jurisdictions board members of companies academics researchers and students Electricity Decentralization in the European Union Rafael Leal-Arcas, 2023-07-10 Electricity Decentralization in the European Union Towards Zero Carbon and Energy Transition Second Edition examines progress in decentralization across the European Union with each chapter focusing on developments and innovations in a specific country Sections provide an overview of the current role and state of smart grids the conceptualization of energy transition and specific cases across all EU states Across the chapters regulatory frameworks are assessed to identify to what extent it is conducive to decentralization with specific outcomes of decentralization covered in detail including deployment of smart grids and meters demand response electric vehicles and storage The book highlights how specific EU member states are progressing towards deployment of these tools and technologies along with the specific needs and regulatory barriers in each and recommendations for how regulation can be more encouraging In addition electricity interconnections in the EU are considered as a vital step towards decentralization in order to boost energy security and energy efficiency Finally the book includes a detailed examination of data protection concerns that arise from the advent of new technologies that collect personal information such as smart grids assessing current regulation on data protection and identifying areas for improvement as well as innovative finance options for sustainable energy Analyzes the regulatory environment with regard to decentralization Explores new tools and technologies to facilitate decentralization along with current progress in each Addresses barriers and suggests improvements across tools technologies and regulations **Cross-Border Mergers in** Europe: Volume 1 Dirk Van Gerven, 2010-03-04 This discussion of the Cross Border Merger Directive and its implementing legislation in each Member State of the European Union and the European Economic Area provides companies and their advisors with useful insight into the legal framework applicable to and the tax treatment of cross border mergers throughout the European Economic Area Analysis of the Community rules laid down in the Cross Border Merger Directive and the Community rules on the tax treatment of cross border mergers is complemented by chapters on the implementing legislation in each Member State prepared in accordance with a common format and contributed by a practitioner from each state Annexes contain the Cross Border Merger Directive Annex I the Parent Subsidiary Directive Annex II and a list of the implementing legislation in each Member State Annex III The European Legal 500,2006 Geopolitical Risk.

Sustainability and "Cross-Border Spillovers" in Emerging Markets, Volume II Michael I. C. Nwogugu, 2022-01-01 Many emerging market countries are bank based economies and are increasingly affected by geopolitical risks U S dollar dynamics regulations preferential trade agreements PTAs MNCs that often function like international organizations social networks labor dynamics cross border spillovers and the inefficient expansion of formal informal microfinance Country risks informal economies that account for 20 50 percent of the national economy of many emerging market countries investor protection enforcement commitment compliance costs sustainability environmental social economic and political sustainability economic growth political stability financial stability geopolitical risk social networks household economics inequality and international trade outcomes can vary dramatically across many DECs and LDECs due to these phenomena The COVID 19 pandemic has illustrated the many problems inherent in political systems economic policy and governments emergency powers during pandemics epidemics and economic financial crisis This second volume focuses on geopolitical risks that are intertwined with constitutional political economy and labor issues alongside addressing some of the financial and constitutional crises that occurred in Europe Asia and the U S during 2007 2020 This book provides analysis of complex systems and the preferences and reasoning of state government and corporate actors in order to develop better artificial intelligence and decision system models of geopolitical risk public policy and international capital flows all of which are increasingly important decision factors for investment managers boards of directors and government officials Laundering Wouter H. Muller, Christian H. Kalin, John G. Goldsworth, 2007-06-05 Anti Money Laundering is the definitive reference on money laundering and practice First an outline will be given of the general approach taken by supra national organisations like the United Nations and the European Council Next the approach taken by international organisations and initiatives on the basis of the supra national initiatives will be outlined by senior members of those organisations A number of countries will then describe their specific prevention legislation Countries involved will all be member countries of the FATF Financial Action Task Force on Money Laundering Finally there will be an overview to enable the reader to make a comparison between the most important topics of money laundering legislation and rules in the different countries

Cross-Border Mergers in Europe: Volume 2 Dirk Van Gerven, 2011-09-08 This discussion of the Cross Border Merger Directive and its implementing legislation in each Member State of the European Union and the European Economic Area provides companies and their advisors with useful insight into the legal framework applicable to and the tax treatment of cross border mergers throughout the European Economic Area Analysis of the Community rules laid down in the Cross Border Merger Directive and the Community rules on the tax treatment of cross border mergers is complemented by chapters on the implementing legislation in each Member State prepared in accordance with a common format and contributed by a practitioner from each state Annexes contain the Cross Border Merger Directive Annex I the Parent Subsidiary Directive Annex II and a list of the implementing legislation in each Member State Annex III Privacy in the

Digital Environment, European Rules of Civil Procedure Astrid Stadler, Vincent Smith, Fernando Gascón Inchausti, 2023-11-03 European Rules of Civil Procedure sets out a clear examination of the rules adopted by UNDROIT and the European Law Institute in 2020 Presented within a systematic structure to aid enhanced academic understanding it precisely showcases the substantial comparative knowledge of its authors **Practitioner's Guide to Global Investigations** Judith Seddon, 2018-01-19 There s never been a greater likelihood a company and its key people will become embroiled in a cross border investigation But emerging unscarred is a challenge Local laws and procedures on corporate offences differ extensively and can be contradictory To extricate oneself with minimal cost requires a nuanced ability to blend understanding of the local law with the wider dimension and in particular to understand where the different countries showing an interest will differ in approach expectations or conclusions Against this backdrop GIR has published the second edition of The Practitioner's Guide to Global Investigation The book is divided into two parts with chapters written exclusively by leading names in the field Using US and UK practice and procedure Part I tracks the development of a serious allegation whether originating inside or outside a company looking at the key risks that arise and the challenges it poses along with the opportunities for its resolution It offers expert insight into fact gathering including document preservation and collection witness interviews structuring the investigation the complexities of cross border privilege issues and strategising effectively to resolve cross border probes and manage corporate reputation Part II features detailed comparable surveys of the relevant law and practice in jurisdictions that build on many of the vital issues pinpointed in Part I Capital Markets Law and Compliance Paul Nelson, 2008-01-10 The Markets in Financial Instruments Directive MiFID is a detailed re writing of the regulation of capital markets To the extent those rules permit the Financial Services Authority FSA is also introducing high level principles based regulation In response to this Paul Nelson presents practical guidance on the regulation of the capital markets ranging from new issues and IPOs to investment banking broker dealing and asset management All laws and rules relevant to the regulation of the capital markets are explained and put into context within the economic operation of markets institutions and products the European Single Market the FSA's policies and objectives the historical evolution of the regulations and the general civil and criminal law Drawing on 30 years experience as a practitioner and referring to a vast range of supporting materials the author provides an insightful analysis and critique of the rules the rule makers and the Advanced Introduction to Business and Human Rights Muchlinski, Peter T., 2022-07-19 Focusing on the institutions adoption of the UN Guiding Principles on Business and Human Rights UNGPs in 2011 this timely book charts the field of business and human rights finding that corporate responsibility to respect human rights is gradually evolving into a binding legal duty in both national and international law Following the structure of the UNGPs Peter T Muchlinski also covers the state duty to protect against business violations of human rights the corporate responsibility to respect human rights and access to remedies for corporate violations of human rights **EU Cross-Border Commercial Mediation** Anna

Howard, 2021-01-13 Despite the growing national and international regulatory framework to support cross border mediation the use of such mediation appears to remain stubbornly low This book focuses in particular on the European Union s EU s continued efforts to encourage the use of cross border mediation and examines why such efforts have had a limited impact It does so by drawing on rare and at times surprising detailed insights from in house counsel of multinational companies regarding their use of EU cross border commercial mediation By viewing mediation through the lens of disputants new and important findings regarding why disputants do and do not use cross border mediation have emerged While these findings are of primary relevance to EU policy and practice they have implications far beyond the EU context at a time of increasing international interest in cross border mediation The analysis of the insights provided by the disputants reveals for example the prominent role played by negotiation as a cross border dispute resolution process that negotiation is a key comparator for disputants when considering whether to use mediation how the EU s continued focus on understanding and presenting mediation as an alternative to litigation has resulted in measures which are insufficient to address fully the barriers to the use of mediation intriguing barriers to the use of mediation which arise from the association which disputants draw between mediation and negotiation how the relationship which disputants draw between mediation and negotiation paradoxically raises both opportunities for and obstacles to the increased use of mediation and what disputants need in order to increase their use of cross border mediation The qualitative nature by way of interviews of the research conducted for this book has enabled the identification of nuanced and novel findings regarding mediation s position and potential in cross border dispute resolution These findings together with a detailed examination of the EU Directive on Certain Aspects of Mediation in Civil and Commercial Matters and the EU s continued initiatives to foster the use of mediation form the foundation upon which this book s recommendations are built Changing the frame to view the use of mediation through the disputants perspective as this book does provides the opportunity for the EU to promote cross border mediation in a way which resonates more deeply with disputants and responds more fully to their concerns and needs This thought provoking book will be of interest not only to European and national bodies seeking to promote the use of mediation but clearly also to dispute resolution academics in house counsel and of course mediators and dispute resolution practitioners in general Europe and America, 1992 George N. Yannopoulos, 1991 This record of the proceedings of a colloquium on how the advent of the Single European Market in 1992 will affect the economic relations between the UK and USA examines trade policy issues bilateralism EC policies towards Japan the dollar and monetary integration and USA multinationals Chambers Guide to the UK Legal Profession, 2002

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