

This book provides an analysis of European Union pharmaceutical regulation from a policy-making perspective. The focus is on how the often conflicting agendas of the pharmaceutical industry, the EU member states, the European Commission, and consumer interests are reconciled within the context of regulatory outcomes having to serve public health, healthcare and industrial policy needs within the single market. Breaking with more traditional approaches which stress the economic determinants of pharmaceutical policy, different strands of public policy analysis, regulatory and European integration and policy-making theories are invoked in developing a new conceptual approach to frame the analysis. In-depth case-studies in three key policy areas: patent protection, market authorisation, and pricing and reimbursement, provide substantive support. In providing a unique perspective on how and why EU pharmaceutical policy is made, the book will be of interest to academics, students and policy-practitioners interested in EU policy-making, regulation and public policy analysis.

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