

Contents

1	Introduction	1
1.1	Introduction to the Problem	1
1.2	Theoretical Landscape of Legal Responses	4
1.2.1	International Constitutionalism and Global Administrative Law	5
1.2.2	Legal Pluralism and Systems Theory	8
1.2.3	Spotlight on an Under-Researched Issue	10
1.3	Multilevel Regulation and Legal Certainty	13
1.4	Research Question and Chapter Outline	16
	References	20
2	Conceptualizing Multilevel Regulation	25
2.1	Introduction	25
2.2	Multilevel Governance as an Inspiration for Multilevel Regulation	31
2.3	Defining Multilevel Regulation	35
2.3.1	How Is Multilevel Regulation Different from Multilevel Governance?	35
2.3.2	Towards a Definition of Multilevel Regulation: An Analysis of Key Features	37
2.3.3	Multilevel Regulation: Response from Legal Scholars	39
2.4	Conclusion	41
	References	42
3	Reconceptualizing Legal Certainty: From a Principle of Positive Law to Regulatee Expectations	47
3.1	Introduction	47
3.2	Legal Certainty: Legal Positivist Scholarship	50
3.3	Review of Weber's Ideas	54
3.4	Empirical Understanding of Legal Certainty	60
3.5	Excavating Litigant Notions of Legal Certainty: From the ECJ Case Law	62

3.6	Conclusion	67
	References	68
4	Explanation of Methodological Choices	71
4.1	Introduction	71
4.2	Conceptualization	73
4.3	Research Methods	75
4.4	Operationalization of the Concepts	77
4.5	Recruitment, Sampling and the Research Process	77
4.5.1	Medical Device Case Study	79
4.5.2	Pharmaceutical Case Study	80
4.6	Analytical Strategy	81
	References	82
5	Pilot Study of Regulatory Uncertainty in Marketing Authorization of Medical Products in Europe	85
5.1	Introduction	85
5.2	Aspects of the Regulatory System	88
5.3	Study Results	89
5.3.1	How Has European Regulation Shaped Product Sectors?	89
5.3.2	How Has the European Regulations Impacted Regulatory Uncertainty in These Product Sectors?	92
5.3.3	How Has This Shaped Compliance Strategies?	93
5.4	Discussion and Conclusion	95
	References	97
6	Case Study on Medical Devices Regulation in Europe	99
6.1	Introduction	99
6.2	History of Regulation in the Medical Device Sector	101
6.3	Is the Medical Device Regulatory Space Multilevel in Nature?	103
6.3.1	Rule Making	103
6.3.2	Rule Application	105
6.3.3	Rule Adjudication	106
6.4	What Is the Regulatee Perception of Multilevelness?	108
6.4.1	Rule Making, Rule Application and Rule Adjudication	108
6.4.2	Regulatory Relationships	111
6.5	What Are the Regulatee Perceptions and Expectations of Legal Certainty?	114
6.6	Analysis and Conclusion	117
	References	119
7	Case Study on Pharmaceutical Regulation in Europe	121
7.1	Introduction	121
7.2	History of Regulation in the Pharmaceutical Sector	122

7.3	Is the Pharmaceutical Regulatory Space Multilevel in Nature?	127
7.3.1	Rule Making	127
7.3.2	Rule Application	129
7.3.3	Rule Adjudication	129
7.4	What Is the Regulatee Perception of Multilevelness?	131
7.5	What Are the Regulatee Perceptions and Expectations of Legal Certainty?	132
7.6	Analysis and Conclusion	138
	References	139
8	Case Study on Borderline Medical Products in Europe	141
8.1	Introduction	141
8.2	Borderline Versus Border Area	143
8.3	Judicial Decision-Making on Science Issues	149
8.4	Regulatory Status of EU Guidance Documents	152
8.5	From Recast to Review	155
8.6	Conclusion	158
	References	159
9	Conclusion	161
9.1	Introduction	161
9.2	Response to the Primary Research Question	162
9.3	Theoretical Contributions	165
9.4	Scalability, Limitations and Ideas for Future Research	167
	References	169
	Annexure I: Questionnaire for Medical Devices Case Study	171
	Annexure II: Questionnaire for Pharmaceuticals Case Study	179

European Regulation of Medical Devices and
Pharmaceuticals

Regulatee Expectations of Legal Certainty

Chowdhury, N.

2014, XIII, 185 p. 6 illus., Hardcover

ISBN: 978-3-319-04593-1