

Contents

Foreword	xix
Acknowledgments	xxi
Author	xxiii
Common Abbreviations	xxv
Introduction	xxvii
Chapter 1 Health as a Good	1
1.1 Welfare Economics and Health	1
1.2 Health Care: A Mixed and Collective Good	1
1.3 Equity, Health, and Health Care	2
1.4 Uncertainty Related to the Demand and Results	2
1.5 Physician's Expected Behavior	2
1.6 Supply Condition	2
1.7 Discussion	3
References	3
Chapter 2 Decision-Making in Public Health	5
2.1 Public Health Definition	5
2.1.1 Example of the Influence of Air Pollution on Public Health	5
2.2 Decision-Making in Public Health	5
2.2.1 Organization of Public Health	5
2.2.2 Funding Health Care and Public Health	5
2.2.3 Criteria Used for Priority-Setting and Decision-Making	6
2.2.4 Health Inequalities	7
2.2.5 Monitoring and Evaluation of Public Health Policies	7
2.3 Decision-Making on the Reimbursement	8
2.3.1 Accountability for Reasonableness	8
2.3.2 Transparency	9
2.3.3 Participation	9
2.4 Methods of Incorporating Societal Preferences into Decision-Making	9
References	10
Suggested Reading	11
Chapter 3 Definitions and Concepts	13
3.1 Origin of the Market Access Term	13
3.1.1 Market Access for Goods	13
3.1.1.1 Tariff Measures	13
3.1.1.2 Nontariff Barriers/Measures	13
3.1.2 Application to Health Care	13
3.1.2.1 Tariff Barriers on Pharmaceuticals	13
3.1.2.2 Nontariff Barriers on Pharmaceuticals	14
3.1.2.3 Health Care Market Specificities	14
3.2 Market Access Key Concepts	16
3.2.1 What Is Value?	16
3.2.2 What Is Access?	17
3.3 Market Access Definition	17
3.3.1 Market Access and the Structure of Health Care System	19
3.3.1.1 Publicly Funded Health Care Systems	19
3.3.1.2 Mixed or Private Health Care Systems	20
3.3.1.3 Centralized and Regional Market Access	20
3.4 Cultural Specificities of Market Access	20

3.5	Market Access for Payers	21
3.5.1	Payers Employ Market Access Tools to Control Drug Expenditure.....	21
3.5.2	How to Identify Payers?.....	23
3.5.3	How Payers Assess Value?.....	23
3.5.4	How HTA Evaluation Is Translated into P&R Conditions?	25
3.6	Market Access for Industry.....	25
3.6.1	A New Paradigm.....	25
3.6.2	Organization in the Pharmaceutical Industry.....	25
3.6.3	Objective of Market Access Activities.....	26
	Suggested Reading	26
Chapter 4	HTA Decision Analysis Framework.....	27
4.1	Introduction	27
4.2	History	27
4.3	HTA Processes and Decision Analysis Frameworks	27
4.3.1	National HTA Bodies and Main Assessment Outcomes.....	27
4.3.2	Decisions Impacted by the Assessed Outcomes	29
4.3.3	HTA Core Model® EUnetHTA	29
4.3.4	Evaluation Criteria and Processes for HTA and Pricing.....	29
4.3.4.1	HTA.....	29
4.3.4.2	Pricing	30
4.3.4.3	Market Access Agreements	30
4.3.5	Value Assessment Frameworks.....	31
4.4	France	31
4.4.1	SMR.....	31
4.4.2	ASMR.....	31
4.4.3	Efficiency Notice	32
4.5	England, Ireland, and Wales—Health Technology Appraisal.....	32
4.6	Scotland—New Product Assessment.....	33
4.7	Germany—Additional Benefit and Cost-Benefit.....	33
4.8	Sweden—Marginal Benefit and Cost-Effectiveness.....	33
4.9	Italy—Degree of Innovation and Cost-Effectiveness	34
4.10	Spain—Reimbursement and Pricing Recommendation	34
	Suggested Reading	35
Chapter 5	Early HTA Advice.....	37
5.1	Overview of the Early HTA Advice Pathways	37
5.1.1	HTA-EMA Parallel Scientific Advice.....	37
5.1.2	MultiHTA Advice	37
5.1.3	EUnetHTA Pilot Assessment of Relative Effectiveness	37
5.1.4	Adaptive Pathway	37
5.1.5	Priority Medicines Scheme	37
5.2	National Early HTA Advice Programs	37
5.2.1	France	37
5.2.1.1	Questions to Focus on	42
5.2.1.2	Process.....	42
5.2.1.3	Content of the Dossier.....	42
5.2.2	The United Kingdom	42
5.2.2.1	Questions to Focus on	42
5.2.2.2	Process.....	43
5.2.2.3	Content of the Dossier.....	43
5.2.2.4	Light Scientific Advice.....	43
5.2.3	Germany.....	44

5.3	Strategic Considerations.....	44
5.3.1	Multidisciplinary Approach.....	44
5.3.2	Briefing Book Is the Cornerstone of Early HTA Advice.....	44
5.3.3	How to Choose the Right Option for Early HTA Advice.....	44
5.3.4	Types of Risk for the Company When Considering Early HTA Advice.....	45
5.3.4.1	Target Population Related Risk.....	45
5.3.4.2	Development Plan Related Risk.....	45
5.4	Conclusions.....	46
	References.....	46
Chapter 6	Overview of Market Access Agreements.....	47
6.1	Background.....	47
6.2	Rationale behind MAAs.....	47
6.3	Different Definitions and Taxonomies of MAAs.....	47
6.3.1	Different Definitions.....	47
6.3.2	A Possible Definition.....	49
6.3.3	Different Taxonomies.....	49
6.3.4	Simplified Taxonomy.....	49
6.3.4.1	Commercial Agreement.....	51
6.3.4.2	Payment for Performance.....	51
6.3.4.3	Coverage with Evidence Development.....	52
6.4	Payers' and Manufacturers' Motivations to Implement MAAs.....	53
6.4.1	The Increasingly Cost-Sensitive Environment.....	53
6.4.2	The Uncertainty Related to Drug's Performance.....	53
6.4.3	The "Trust Crisis".....	54
6.5	International Comparison of MAA Health Policies.....	54
6.5.1	MAAs across Countries.....	54
6.5.2	Some Countries Are More Resistant Than Others.....	56
6.5.3	Regional MAAs Growth in Europe.....	56
6.5.3.1	Formularies in Italy Are Subject to Regional Influence.....	57
6.5.3.2	Regional MAA in Sweden.....	58
6.6	Best Practice of MAAs.....	59
6.6.1	The Rationale behind MAAs.....	59
6.6.1.1	When Should MAAs Be Considered?.....	59
6.6.2	The Implementation Process.....	60
6.6.2.1	Requirements for Implementing MAAs.....	60
6.6.2.2	Challenges in MAAs Implementation.....	60
6.6.3	Evaluation.....	61
6.7	Impact of MAAs on Product Uptake.....	61
6.7.1	Example of MS MAA in the United Kingdom: Impact on Sales.....	61
6.7.2	Example of Bevacizumab's Uptake in Metastatic Colorectal Cancer across EU Countries.....	62
6.7.3	Etanercept MAA in Germany.....	63
6.8	Some Specific Case Studies.....	63
6.8.1	Example of CED in the United Kingdom: Use of β -Interferons and Glatiramere for the Treatment of MS in the United Kingdom.....	63
6.8.1.1	Performance of MAAs.....	64
6.8.2	Examples of CEDs in France.....	64
6.8.2.1	Performance of MAAs.....	65
6.8.3	Examples of CEDs in Sweden.....	65
6.8.3.1	Performance of MAAs.....	65
6.8.4	Example of MAAs in Italy.....	65
6.8.4.1	Performance of MAAs.....	66
6.8.5	Financing of MAA Drugs.....	66

6.9	Overview of MAA Trends in Other Countries	66
6.9.1	MAA Is a Growing Phenomenon in Various Countries	66
6.9.2	MAAs in Australia	66
6.9.3	MAAs in Latin America.....	67
6.9.4	India: A Different MA Pathway	67
6.9.5	MA in South Korea	67
6.10	Perspectives	68
6.10.1	MAA Is a Growing Trend and Is Shifting toward Conditional Access.....	68
6.10.2	Challenges with MAAs.....	68
6.11	Conclusion: MAA, a Temporary Solution?.....	68
6.11.1	A Paradigm Shift in the Pharmaceutical Industry	69
6.11.2	From a Decision Point to a Decision Window	69
6.11.3	Which MAAs in the Future?	69
	References	69
Chapter 7	External Reference Pricing.....	71
7.1	Definition of External Reference Pricing	71
7.2	ERP in Europe	71
7.2.1	National Legal Framework.....	71
7.2.2	Scope of ERP	72
7.2.3	Composition of the Country Basket.....	72
7.2.4	Price Calculation and Selection of Reference Products	72
7.3	ERP Processes in Non-European Countries.....	73
7.3.1	Australia	73
7.3.2	Canada.....	73
7.3.3	Japan.....	73
7.3.4	South Korea.....	73
7.3.5	Mexico.....	74
7.3.6	New Zealand.....	74
7.3.7	Turkey.....	74
7.4	Concerns Related to ERP	74
7.4.1	Potential Consequences of ERP	74
7.4.1.1	Patient Access to Medicine.....	75
7.4.1.2	Affordability	75
7.4.1.3	Industry Revenue and Sustainability	75
7.5	VBP and ERP	76
7.5.1	ERP as an Alternative to VBP	76
7.5.2	ERP and VBP Combination	76
	References	76
Chapter 8	Gap between Payers and Regulators	79
8.1	Introduction	79
8.2	Uncertainty versus Risk	79
8.3	Payers versus Regulators	79
8.4	Sources of Uncertainty	80
8.4.1	Regulators	80
8.4.2	HTA Bodies/Payers	80
8.5	Risk Management of Drug Value Uncertainty—HTA/Payer Level	80
8.5.1	Population.....	80
8.5.2	Comparator.....	80
8.5.3	Design.....	81
8.5.4	Outcome	81
8.5.5	Indirect Comparison	82

8.6	Risk Management Tools.....	82
8.6.1	Regulators.....	82
8.6.2	HTA Bodies and Payers.....	84
8.7	Type of Studies Requested by HTA Bodies/Payers to Reduce the Uncertainty.....	85
8.8	Case Studies of Gaps between Regulatory and HTA/Payer Approval.....	86
8.8.1	Drugs General Characteristics and Approval History.....	86
8.8.2	Regulatory versus Payers' Evaluations.....	86
8.8.3	Discussion of Case Studies.....	89
8.9	Conclusions.....	90
	References.....	90
Chapter 9	Early Access Programs.....	91
9.1	Overview.....	91
9.2	Types of EAPs: Nominative and Cohort.....	92
9.3	Global EAP Trends.....	92
9.4	Key Success Factors and EAP Management.....	92
	References.....	96
Chapter 10	Market Access of Orphan Drugs.....	97
10.1	Definitions of Orphan Drugs.....	97
10.1.1	US Definition.....	97
10.1.2	EU Definition.....	97
10.1.3	Japan.....	97
10.1.4	South Korea.....	97
10.2	The Legal Frameworks for Licensing and Assessment of Orphan Drugs and Development Incentives.....	97
10.2.1	The European Union.....	97
10.2.2	France.....	98
10.2.2.1	Compassionate Use.....	98
10.2.2.2	Development Incentives.....	98
10.2.3	Germany.....	99
10.2.3.1	Compassionate Use.....	99
10.2.3.2	Development Incentives.....	99
10.2.4	Spain.....	99
10.2.4.1	Compassionate Use.....	99
10.2.4.2	Development Incentives.....	99
10.2.5	Italy.....	100
10.2.5.1	Compassionate Use.....	100
10.2.5.2	Development Incentives.....	100
10.2.6	The United Kingdom.....	100
10.2.6.1	Scotland.....	100
10.2.6.2	England and Wales.....	100
10.2.7	Asia.....	101
10.2.7.1	Japan.....	101
10.2.7.2	South Korea.....	101
10.3	The Pricing Process of Orphan Drugs.....	101
10.3.1	France.....	101
10.3.2	Germany.....	102
10.3.3	Italy.....	102
10.3.4	Spain.....	102
10.3.5	The United Kingdom.....	102
10.3.6	Japan.....	102
10.3.7	South Korea.....	103

10.4	Comparison of Prices of Orphan Drugs.....	103
10.5	The HTA Framework for Orphan Drugs and Ultra-Orphan Drugs.....	103
10.6	The Concept of Ethics and Equity for Orphan Drugs.....	103
10.7	Potential Alternative Methods for HTA and Pricing of Orphan Drugs.....	103
10.8	The Issues with Prices of Orphan Drugs.....	104
10.9	Future Perspectives.....	104
10.10	Conclusion.....	105
	References.....	105
Chapter 11	Market Access of Vaccines in Developed Countries.....	107
11.1	Introduction.....	107
11.1.1	Definition and Classifications.....	107
11.1.2	Preventive Vaccines.....	107
11.1.3	Therapeutic Vaccines.....	107
11.2	Vaccines' Specifics.....	108
11.2.1	Development.....	108
11.2.2	Safety.....	108
11.2.3	Benefits and Cost-Effectiveness.....	108
11.2.3.1	Humanistic Benefits.....	108
11.2.3.2	Economic Benefit.....	108
11.2.3.3	Cost-Effectiveness.....	109
11.2.4	Market Typology.....	109
11.3	Overview of Vaccines' Market Access in Developed Countries.....	109
11.3.1	Overview of NITAGs' Processes.....	109
11.3.1.1	NITAGs' Members.....	109
11.3.1.2	Operations.....	109
11.3.1.3	Decision Criteria.....	109
11.3.2	Implementation of NITAGs' Recommendations.....	110
11.3.3	Time to Market.....	110
11.4	Overview of Vaccines' Market Access in a Selection of European Countries and the United States.....	110
11.4.1	Austria.....	110
11.4.2	Denmark.....	110
11.4.3	France.....	111
11.4.4	Germany.....	111
11.4.5	Italy.....	111
11.4.6	The Netherlands.....	112
11.4.7	Spain.....	112
11.4.8	Sweden.....	112
11.4.9	The United Kingdom.....	113
11.4.10	The United States.....	114
	References.....	115
Chapter 12	France.....	117
12.1	Stakeholders.....	117
12.1.1	Names of National Pricing and Reimbursement Decision Makers.....	117
12.1.2	Names of National Health Technology Assessment Agencies.....	117
12.1.3	Names of Other Key Stakeholders (Regional/Local Level).....	117
12.2	Pricing and Reimbursement Policies.....	117
12.2.1	Overview of the System.....	117
12.2.2	Reimbursement Process.....	118
12.2.3	Pricing Process.....	118
12.3	Time to Market.....	118
12.4	Price Regulations.....	119
12.4.1	Pricing Policy Following the Marketing Authorization.....	119
12.4.2	External Reference Pricing.....	119

12.4.3	Internal Reference Pricing	119
12.4.4	Price Control at Ex-Factory Price Level	119
12.4.5	Price Control at Wholesale Level	119
12.4.6	Price Control at Pharmacy Retail Level.....	119
12.4.7	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	119
12.5	Reimbursement Specificities	119
12.6	Characteristics of Public Tendering	119
12.7	Expenditure Controls (Supply Side)	120
12.7.1	Discounts/Rebates.....	120
12.7.2	Clawback	120
12.7.3	Payback.....	120
12.7.4	Price-Volume Agreements	120
12.7.5	Other Market Access Agreements.....	120
12.7.6	Price Freezes and Cuts.....	120
12.8	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	120
12.8.1	Wholesaler and Pharmacy Mark-Up.....	120
12.8.2	Generic Substitution	121
12.8.3	INN Prescribing	121
12.8.4	Prescription Guidelines.....	121
12.8.5	Monitoring of Prescribing Behavior	121
12.8.6	Pharmaceutical Budgets Defined for Physicians	121
12.8.7	Prescription Quotas.....	121
12.8.8	Financial Incentives for Physicians	121
12.8.9	Financial Incentives for Pharmacists	121
12.8.10	Copayment for Patients.....	121
	References	121
	Further Reading.....	122
Chapter 13	Germany	123
13.1	Stakeholders	123
13.1.1	Names of National Pricing and Reimbursement Decision Makers	123
13.1.2	Names of National Health Technology Assessment Agencies	123
13.1.3	Names of Other Key Stakeholders (Regional/Local Level)	123
13.2	Pricing and Reimbursement Policies	123
13.2.1	Overview of the System.....	123
13.2.2	Reimbursement Process.....	123
13.2.3	Pricing Process.....	124
13.3	Time to Market.....	124
13.4	Price Regulations	124
13.4.1	Pricing Policy Following the Marketing Authorization	124
13.4.2	External Reference Pricing	124
13.4.3	Internal Reference Pricing	124
13.4.4	Price Control at Ex-Factory Price Level.....	124
13.4.5	Price Control at Wholesale Level	124
13.4.6	Price Control at Pharmacy Retail Level.....	124
13.4.7	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	125
13.5	Reimbursement Specifics	125
13.6	Characteristics of Public Tendering	125
13.6.1	Expenditure Controls Discounts/Rebates	125
13.6.2	Clawback	125
13.6.3	Payback.....	125
13.6.4	Price-Volume Agreements	125
13.6.5	Other Market Access Agreements.....	125
13.6.6	Price Freezes and Cuts.....	125

13.7	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	125
13.7.1	Wholesaler Mark-Up.....	125
13.7.2	Pharmacy Mark-Up.....	125
13.7.3	Generic Substitution.....	125
13.7.4	International Nonproprietary-Name Prescribing	125
13.7.5	Prescription Guidelines	126
13.7.6	Monitoring of Prescribing Behavior	126
13.7.7	Pharmaceutical Budgets Defined for Physicians	126
13.7.8	Prescription Quotas	126
13.7.9	Financial Incentives for Physicians.....	126
13.7.10	Financial Incentives for Pharmacists	126
13.7.11	Copayment for Patients	126
	References	126
Chapter 14	Italy.....	127
14.1	Stakeholders	127
14.1.1	Names of National Pricing and Reimbursement Decision Makers.....	127
14.1.2	Names of National Health Technology Assessment Agencies.....	127
14.1.3	Other Key Stakeholders at National Level.....	127
14.1.4	Regional and Local Stakeholders.....	127
14.2	Pricing and Reimbursement of Pharmaceuticals in Italy	127
14.2.1	Overview of the System	127
14.2.2	The Process	128
14.2.3	Reimbursement Classes	128
14.3	Time to Market Access for Drugs	128
14.4	Price Regulation	129
14.4.1	Pricing Policy Following the Marketing Authorization	129
14.4.2	External Reference Pricing	129
14.4.3	Internal Reference Pricing	129
14.4.4	Price Control (at Ex-Factory, Wholesale, and Pharmacy Retail).....	129
14.4.5	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry.....	129
14.5	Cost-Containment Policies.....	129
14.5.1	Prescription Guidelines.....	129
14.5.2	Discounts/Rebates.....	129
14.5.3	Payback	129
14.5.4	Price-Volume Agreements.....	129
14.5.5	Other Market Access Agreements.....	129
14.5.6	Monitoring of Prescribing Behavior	130
14.5.7	Public Tenders.....	130
14.5.8	Generic Substitution.....	130
14.5.9	Copayment for Patients	130
14.6	Policies Targeted at Wholesalers, Pharmacists	130
14.6.1	Wholesaler Mark-Up.....	130
14.6.2	Pharmacy Mark-Up.....	130
	References	130
Chapter 15	Spain.....	131
15.1	Stakeholders	131
15.1.1	Names of National Pricing and Reimbursement Decision Makers.....	131
15.1.2	Names of National Health Technology Assessment Agencies.....	131
15.1.3	Names of Other Key Stakeholders (Regional/Local Level).....	131
15.2	Pricing and Reimbursement Policies	131
15.2.1	Overview of the System	131
15.2.2	Reimbursement Process	131
15.2.3	Pricing Process.....	132

15.3	Time to Market	132
15.4	Price Regulations	132
15.4.1	Pricing Policy Following the Marketing Authorization	132
15.4.2	External Reference Pricing	132
15.4.3	Internal Reference Pricing	132
15.4.4	Price Control at Ex-Factory Price Level	132
15.4.5	Price Control at Wholesale Level	132
15.4.6	Price Control at Pharmacy Retail Level	132
15.4.7	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	132
15.5	Reimbursement Specificities	132
15.6	Characteristics of Public Tendering	132
15.7	Expenditure Controls	133
15.7.1	Discounts/Rebates	133
15.7.2	Clawback	133
15.7.3	Payback	133
15.7.4	Price-Volume Agreements	133
15.7.5	Other Market Access Agreements	133
15.7.6	Price Freezes and Cuts	133
15.8	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	133
15.8.1	Wholesaler Mark-Up	133
15.8.2	Pharmacy Mark-Up	133
15.8.3	Generic Substitution	133
15.8.4	International Nonproprietary Name (INN) Prescribing	133
15.8.5	Prescription Guidelines	133
15.8.6	Monitoring of Prescribing Behavior	133
15.8.7	Pharmaceutical Budgets Defined for Physicians	133
15.8.8	Prescription Quotas	134
15.8.9	Financial Incentives for Physicians	134
15.8.10	Financial Incentives for Pharmacists	134
15.8.11	Copayment for Patients	134
	References	134
Chapter 16	Sweden	135
16.1	Stakeholders	135
16.1.1	National Pricing and Reimbursement Decision Makers	135
16.1.2	National Health Technology Assessment Agencies	135
16.1.3	Other Key Stakeholders	135
16.2	Pricing and Reimbursement Policies	135
16.2.1	Overview of the System	135
16.2.2	Reimbursement Process	136
16.2.3	Pricing Process	136
16.2.4	Pharmaco-Economic Assessment	136
16.3	Time to Market	137
16.4	Price Regulations	137
16.4.1	Pricing Policy Following the Marketing Authorization	137
16.4.2	External Reference Pricing	137
16.4.3	Internal Reference Pricing	137
16.4.4	Price Control at Ex-Factory Price Level	137
16.4.5	Price Control at Wholesale Level	137
16.4.6	Price Control at Pharmacy Retail Level	137
16.4.7	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	137
16.5	Reimbursement Specificities	138
16.6	Characteristics of Public Tendering	138
16.7	Expenditure Controls	138
16.7.1	Discounts/Rebates	138

16.7.2	Clawback	138
16.7.3	Payback.....	138
16.7.4	Price-Volume Agreements	138
16.7.5	Other Market Access Agreements.....	138
16.7.6	Price Freezes and Cuts.....	138
16.8	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	138
16.8.1	Wholesaler Mark-Up	138
16.8.2	Pharmacy Mark-Up.....	138
16.8.3	Generic Substitution	138
16.8.4	International Nonproprietary Name (INN) Prescribing.....	138
16.8.5	Prescription Guidelines.....	138
16.8.6	Monitoring of Prescribing Behavior	138
16.8.7	Pharmaceutical Budgets Defined for Physicians	139
16.8.8	Prescription Quotas.....	139
16.8.9	Financial Incentives for Physicians	139
16.8.10	Financial Incentives for Pharmacists	139
16.8.11	Copayment for Patients.....	139
	References	139
Chapter 17	United Kingdom	141
17.1	Stakeholders	141
17.1.1	National Pricing and Reimbursement Decision Makers.....	141
17.1.2	National Health Technology Assessment (HTA) Agencies	141
17.2	Pricing and Reimbursement Policies.....	141
17.2.1	Overview of the System.....	141
17.2.2	Reimbursement Process.....	141
17.2.3	Pricing Process.....	142
17.3	Time to Market	142
17.4	Price Regulations.....	142
17.4.1	Pricing Policy Following the Marketing Authorization.....	142
17.4.2	Reference Pricing.....	142
17.4.3	Price Control.....	142
17.4.4	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	142
17.5	Reimbursement Specifics	143
17.6	Characteristics of Public Tendering.....	143
17.6.1	Applied to Hospital Care	143
17.6.2	Applied to Ambulatory Care.....	143
17.7	Expenditure Controls (Supply Side).....	143
17.7.1	Discounts/Rebates.....	143
17.7.2	Clawback	143
17.7.3	Payback.....	143
17.7.4	Price-Volume Agreements	143
17.7.5	Other Market Access Agreements.....	143
17.7.6	Price Freezes and Cuts.....	144
17.8	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	144
17.8.1	Wholesaler Mark-Up	144
17.8.2	Pharmacy Mark-Up.....	144
17.8.3	Generic Substitution	144
17.8.4	International Nonproprietary Name (INN) Prescribing.....	144
17.8.5	Prescription Guidelines.....	144
17.8.6	Monitoring of Prescribing Behavior	144
17.8.7	Pharmaceutical Budgets Defined for Physicians	144
17.8.8	Financial Incentives for Physicians	144
17.8.9	Copayment for Patients.....	144
	References	145

Chapter 18	Belgium	147
18.1	Stakeholders	147
18.1.1	Names of National Pricing and Reimbursement Decision Makers	147
18.1.2	Names of National Health Technology Assessment Agencies	147
18.1.3	Names of Other Key Stakeholders (Regional/Local Level)	147
18.2	Pricing and Reimbursement Policies Overview	147
18.2.1	Overview of the System	147
18.2.2	Reimbursement Process	148
18.2.3	Pricing Process	148
18.3	Time to Market	148
18.4	Price Regulations	149
18.4.1	Pricing Policy Following the Marketing Authorization	149
18.4.2	External Reference Pricing	149
18.4.3	Internal Reference Pricing	149
18.4.4	Price Control at Ex-Factory Price Level	149
18.4.5	Price Control at Wholesale Level	149
18.4.6	Price Control at Pharmacy Retail Level	149
18.4.7	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	149
18.5	Reimbursement Specifics	149
18.5.1	Characteristics of Public Tendering	149
18.5.2	Expenditure Controls Discounts/Rebates	149
18.5.3	Clawback	149
18.5.4	Payback	149
18.5.5	Price-Volume Agreements	149
18.5.6	Other Market Access Agreements	149
18.5.7	Price Freezes and Cuts	150
18.6	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	150
18.6.1	Wholesaler Mark-Up	150
18.6.2	Pharmacy Mark-Up	150
18.6.3	Generic Substitution	150
18.6.4	International Nonproprietary Name Prescribing	150
18.6.5	Prescription Guidelines	150
18.6.6	Monitoring of Prescribing Behavior	150
18.6.7	Pharmaceutical Budgets Defined for Physicians	150
18.6.8	Prescription Quotas	150
18.6.9	Financial Incentives for Physicians	151
18.6.10	Financial Incentives for Pharmacists	151
18.6.11	Copayment for Patients	151
18.6.12	Special Funding Procedure for Individual Patients	151
	References	151
Chapter 19	The United States	153
19.1	Stakeholders	153
19.1.1	Names of National Pricing and Reimbursement Decision Makers	153
19.1.2	Names of National Health Technology Assessment Agencies	153
19.1.3	Names of Other Key Stakeholders (Regional/Local Level)	153
19.2	Overview of Pricing and Reimbursement Policies	153
19.2.1	Overview of the System	153
19.2.2	Reimbursement Process	154
19.2.3	Pricing Process	154
19.3	Time to Market	154
19.4	Price Regulations	154
19.4.1	Pricing Policy Following the Marketing Authorization	154
19.4.2	External Reference Pricing	154

19.4.3	Internal Reference Pricing	154
19.4.4	Price Control at Ex-Factory Price Level	154
19.4.5	Price Control at Wholesale Level	154
19.4.6	Price Control at Pharmacy Retail Level.....	154
19.4.7	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	154
19.5	Reimbursement Specificities	154
19.6	Characteristics of Public Tendering.....	154
19.7	Expenditure Controls.....	155
19.7.1	Discounts/Rebates.....	155
19.7.2	Clawback	155
19.7.3	Payback.....	155
19.7.4	Price-Volume Agreements	155
19.7.5	Other Market Access Agreements.....	155
19.7.6	Price Freezes and Cuts	155
19.8	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	155
19.8.1	Wholesaler Mark-Up	155
19.8.2	Pharmacy Mark-Up.....	155
19.8.3	Generic Substitution	155
19.8.4	International Nonproprietary Name (INN) Prescribing.....	155
19.8.5	Prescription Guidelines.....	155
19.8.6	Monitoring of Prescribing Behavior	155
19.8.7	Pharmaceutical Budgets Defined for Physicians	155
19.8.8	Prescription Quotas.....	156
19.8.9	Financial Incentives for Physicians	156
19.8.10	Financial Incentives for Pharmacists	156
19.8.11	Copayment for Patients.....	156
	References	156
Chapter 20	Japan.....	159
20.1	Stakeholders	159
20.1.1	National Pricing and Reimbursement Decision Makers	159
20.1.2	National Health Technology Assessment Agencies.....	159
20.1.3	Other Key Stakeholders (Regional/Local Level)	159
20.2	Overview of Pricing and Reimbursement Policies	159
20.2.1	Overview of the System.....	159
20.2.2	Reimbursement Process.....	159
20.2.3	Pricing Process	159
20.3	Time to Market.....	159
20.4	Price Regulations.....	159
20.4.1	Pricing Policy Following the Marketing Authorization.....	159
20.4.2	External Reference Pricing	160
20.4.3	Internal Reference Pricing	160
20.4.4	Price Control at Ex-Factory Price Level.....	160
20.4.5	Price Control at Wholesale Level	160
20.4.6	Price Control at Pharmacy Retail Level.....	160
20.4.7	Mandatory Price Reduction on Brand Price after Generic/Biosimilar Entry	160
20.5	Reimbursement Specifics	160
20.6	Characteristics of Public Tendering	160
20.7	Expenditure Controls.....	160
20.7.1	Discounts/Rebates.....	160
20.7.2	Clawback	160
20.7.3	Payback.....	160
20.7.4	Price-Volume Agreements	160
20.7.5	Other Market Access Agreements.....	160
20.7.6	Price Freezes and Cuts	160

20.8	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients.....	160
20.8.1	Wholesaler and Pharmacy Mark-Up.....	160
20.8.2	Generic Substitution	161
20.8.3	International Nonproprietary Name (INN) Prescribing.....	161
20.8.4	Prescription Guidelines.....	161
20.8.5	Monitoring of Prescribing Behavior.....	161
20.8.6	Pharmaceutical Budgets Defined for Physicians	161
20.8.7	Prescription Quotas.....	161
20.8.8	Financial Incentives for Physicians	161
20.8.9	Financial Incentives for Pharmacists	161
20.8.10	Copayment for Patients.....	161
	References	161
Chapter 21	China	163
21.1	Stakeholders	163
21.1.1	Names of National Pricing and Reimbursement Decision Makers	163
21.1.2	Names of National Health Technology Assessment Agencies	163
21.1.3	Names of Other Key Stakeholders (Regional/Local Level).....	163
21.2	Pricing and Reimbursement Policies	163
21.2.1	Overview of the System.....	163
21.2.2	Reimbursement Process.....	163
21.2.3	Pricing Process.....	163
21.3	Time to Market	164
21.4	Price Regulations.....	164
21.4.1	Pricing Policy Following the Marketing Authorization.....	164
21.4.2	External Reference Pricing	164
21.4.3	Internal Reference Pricing	164
21.4.4	Price Control at Ex-Factory Price Level.....	164
21.4.5	Price Control at Wholesale Level	164
21.4.6	Price Control at Pharmacy Retail Level.....	164
21.4.7	Mandatory Price Reduction of Price of On-Patent Drugs after Generic/Biosimilar Entry	164
21.5	Reimbursement Specificities	164
21.6	Characteristics of Public Tendering.....	164
21.7	Expenditure Controls.....	164
21.7.1	Discounts/Rebates.....	164
21.7.2	Clawback	164
21.7.3	Payback.....	164
21.7.4	Price-Volume Agreements	164
21.7.5	Other Market Access Agreements.....	164
21.7.6	Price Freezes and Cuts.....	164
21.8	Policies Targeted at Wholesalers, Pharmacists, Physicians, and Patients	165
21.8.1	Wholesaler and Pharmacy Mark-Up.....	165
21.8.2	Generic Substitution	165
21.8.3	International Nonproprietary Name (INN) Prescribing.....	165
21.8.4	Prescription Guidelines.....	165
21.8.5	Monitoring of Prescribing Behavior.....	165
21.8.6	Pharmaceutical Budgets Defined for Physicians	165
21.8.7	Prescription Quotas.....	165
21.8.8	Financial Incentives for Physicians	165
21.8.9	Financial Incentives for Pharmacists	165
21.8.10	Copayment for Patients.....	165
21.8.11	Changes in the Pricing Mechanism	165
	References	166
	Epilogue	167
	Index.....	169